EPA REGISTRATION NUMBER 100-1309 Vol. 2

Material to be added to an e-Jacket/Jacket

Reg. No. 100-1309 D# 444250

Description: Correct rate for 16-18" trees

1. ☑ Placement within the e-Jacket/jacket:
   - ☑ Default: (chronological, top = newest)
   - ☐ File Location: (PDF page number, i.e., "before page 45")

2. ☑ Send to Data Extraction contractors this material:
   - ☑ Newly stamped accepted label
   - ☐ Notification
   - ☐ New CSF
   - ☐ Other: _____

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name: Tom Harris
Phone: 308-9423 Division: RD Date: 4/18/11

Created April 18, 2011

stamped label 100-1309, 16-18" rate correction

Thomas Harris to tom.parshley 04/18/2011 11:00 AM

Tom,

Attached please find stamped accepted label and letter for you 1/6/11 amendment to correct the rates for 16-18" trees. Sorry this took so long; I had misfiled it on my desk and didn't notice it until I ran a pending action report. Hope that didn't cause you any inconvenience.

Unless you request a paper copy, this email will constitute the official delivery of this document.

000100-01309.20110418.rate correction.amd.a.stamped label.ocr.pdf

Tom Harris
EPA/OCSPP/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

4/18/2011

Tom Parshley
Syngenta Crop Protection, Inc.
PO Box 18300
Greensboro, NC 27419

re: Emamectin Benzoate 4.0% Tree Injection, EPA Reg. # 100-1309
label amendment submitted 1/6/2011 (D#444250)
accepted

Dear Mr. Parshley:

The revised labeling submitted in connection with the registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is ACCEPTABLE. This label amendment corrects a minor rate error for 16-18" diameter trees.

Submit two (2) copies of your final printed labeling incorporating the above changes prior to releasing your product for shipment. If the above provisions are not complied with the registration will be subject to cancellation in accordance with FIFRA Section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A copy of the label stamped "accepted" is enclosed for your records. If you have any questions please contact Tom Harris at (703) 308-9423 or harris.thomas@epa.gov

Yours truly,

Thomas C. Harris
Biologist
Insecticide-Rodenticide Branch
Registration Division (7505P)

enclosure

(Master label)

RESTRICTED USE PESTICIDE
DUE TO ACUTE TOXICITY TO HUMANS
FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION, AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION.

Emamectin Benzoate 4.0% Tree Injection

Injected insecticide for two year control of listed arthropod pests in deciduous, coniferous, and palm trees

Active Ingredient:	
Emamectin Benzoate[1]	4.0%
Other Ingredients:	96.0%
Total:	100.0%

[1]CAS No.155569-91-8
Contains 0.36 lbs. emamectin per gallon.

KEEP OUT OF REACH OF CHILDREN.

WARNING/AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

See additional precautionary statements and directions for use on label[in booklet].

EPA Reg. No. 100-1309

EPA Est. xxxxx

Product of xxxxx
Formulated in xxxxx

SCP 1309A-M(draft rate)

ACCEPTED
APR 18 2011
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under:

EPA. Reg. No: 100-1309

Net Contents

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING/AVISO

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear. Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID	
If in eyes	•Hold eye open and rinse slowly and gently with water for 15-20 minutes. •Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. •Call a poison control center or doctor for treatment advice.
If swallowed	•Call poison control center or doctor immediately for treatment advice. •Have person sip glass of water if able to swallow. •Do not induce vomiting unless told to do so by the poison control center or doctor. •Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN

Early signs of intoxication include dilation of pupils, muscular incoordination, and muscular tremors. Vomiting within one-half hour of exposure can minimize toxicity following accidental ingestion of the product; rapidly after exposure (< 15 minutes) administer repeatedly medical charcoal in a large quantity of water or ipecac. If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive parenteral fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels and proper respiratory functionality) as indicated by clinical signs, symptoms, and measurements. In severe cases, observations should continue for at least several days until clinical condition is stable and normal. Since emamectin benzoate is believed to enhance GABA activity in animals, it is probably wise to avoid drugs that enhance GABA activity (barbiturates, benzodiazepines, valproic acid) in patients with potentially toxic emamectin benzoate exposure.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
HOT LINE NUMBER For 24-Hour Medical Emergency Assistance (Human or Animal), Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident) Call **1-800-888-8372**

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Chemical–resistant gloves (Category C) such as barrier laminate; butyl rubber ≥14 mils; nitrile rubber ≥14 mils; or neoprene rubber ≥14 mils.
- Shoes and socks
- Protective eyewear

Environmental Hazards

This product is highly toxic to fish, mammals and aquatic invertebrates. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater. This product is highly toxic to bees exposed to direct treatment or residues on blooming trees.

Physical or Chemical Hazards

Do not use or store near heat or open flame.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, Inc. or Seller. To the extent permitted by applicable law, Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law: (1) this warranty does not extend to the use of the product contrary to label instructions or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and, (2) Buyer and User assume the risk of any such use. TO THE EXTENT PERMITTED BY APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.

DIRECTIONS FOR USE
RESTRICTED USE PESTICIDE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

IMPORTANT: Read entire label before using this product. Failure to follow label instructions may result in poor control or tree injury. Failure to follow label directions may cause injury to people, animals and environment.

APPLICATION TO TREES

Emamectin Benzoate 4.0% Tree Injection is for control of mature and immature arthropod pests of deciduous, coniferous, and palm trees, including, but not limited to, those growing in residential and commercial landscapes, parks, plantations, seed orchards, and forested sites (in private, municipal, state, tribal and national areas). Emamectin Benzoate 4.0% Tree Injection contains the active ingredient emamectin benzoate and is formulated to translocate in the tree's vascular system when injected. This product must be placed into active sapwood, and will actively control pests for up to two years.

USE DIRECTIONS

Emamectin Benzoate 4.0% Tree Injection is designed for use with tree injection devices that meet the label and dose requirements [(for example, the Arborjet Tree Injection Systems)] for the control of listed pests of trees. Follow manufacturer's directions for equipment use.

Dosages are based on the Diameter (in inches) of the tree at Breast Height (DBH"). Tree DBH is the outside bark diameter at breast height. Breast height is defined as 4.5 feet (1.37m) above the ground on the uphill side of the tree. For the purposes of determining breast height, the ground includes the duff layer that may be present, but does not include unincorporated woody debris that may rise above the ground line.

The diameter is determined by measuring the circumference of the tree at DBH", and dividing the circumference (in inches) by three (3). To determine DBH" for multi-stemmed woody ornamentals, measure the DBH" for each stem or branch and add together for the total DBH" per tree.

Placement of Application/Injection Sites: Inject at the base of the tree. Inject into the stem within 12" of the soil, into the trunk flare or into tree roots exposing them by shallow excavation. Make applications into intact, healthy sapwood. Do not inject into injured areas or areas with decay. Select injection sites associated with stem growth.

Number of Injection Sites: Work around the tree, spacing injection sites approximately every 6.0 inches of tree's circumference.

Drill Depth: Drill through the bark then 5/8" to 1-5/8" (hardwoods) or 1-5/8" to 2" (conifers) into the sapwood with the appropriate sized drill bit. Use clean, sharp drill bits. Brad point bits are recommended. Precautions should be taken to avoid diseased areas and transferring infected tissues to other injection sites.

Resinous Conifers

In resinous conifers, such as pine and spruce, start the injection immediately after drilling into the sapwood. A prolonged delay may reduce uptake on account of resin flow into opening.

WHEN TO TREAT

Emamectin Benzoate 4.0% Tree Injection contains the active ingredient emamectin benzoate which is a glycoside insecticide. It is active against immature and adult stages of arthropods. The primary route of toxicity is through ingestion.

ENVIRONMENTAL CONDITIONS: Uptake of Emamectin Benzoate 4.0% Tree Injection is dependent upon the tree's transpiration. Transpiration is dependent on a number of abiotic and biotic factors, such as soil moisture, soil and ambient temperature, and time of day. For uptake, apply when soil is moist, soil temperatures are above 45˚F, ambient temperatures are between 40˚ to 90˚F, and during the 24 hour period when transpiration is greatest, typically before 2:00 PM. Applications to drought or heat stressed trees may result in injury to tree tissue, poor treatment and subsequent control. Avoid treating trees that are moisture stressed or suffering from herbicide damage.

MONITOR TREE HEALTH and PEST INFESTATIONS: Effective injection treatment is favored by a full canopy (i.e., leaves) and healthy vascular system. Once these tissues are compromised by arthropod damage (larval galleries, defoliation, leaf mining, etc.) an effective and uniform application of Emamectin Benzoate 4.0% Tree Injection may be difficult to achieve and subsequent control may be poor. Optimally, treatment should be made preventively at least 2 to 3 weeks before arthropods historically infest the host tree. As a result of systemic movement and longevity of Emamectin Benzoate 4.0% Tree Injection in trees, this interval may be extended much earlier to 6 months should tree dormancy, adverse weather, management, asynchronous life cycle of pests, etc., allow earlier application timing.

Emamectin Benzoate 4.0% Tree Injection may also be effective as a remedial treatment against some pests, such as those with slower development or if multiple life stages are susceptible to Emamectin Benzoate 4.0% Tree Injection. Pests that attack the stem and branches such as bark beetles and clearwing borers may disrupt vascular tissue resulting in poor distribution in an infested tree. This includes the initial larval stages of pests, such as bark beetles and clearwing borers, that attack the stem and branches, which may disrupt vascular tissue resulting in poor distribution of the product in an

infested tree. However, control may be achieved if larvae come into contact or feed on Emamectin Benzoate 4.0% Tree Injection treated tissues.

USE

Use as formulated or dilute with equivalent 1 to 3 volumes of water or more, as necessary.

USE RATE TABLE

Tree Diameter (DBH) (Inches)	Low ml. product/tree	Medium ml. product/tree	Medium - High ml. product/tree	High ml. product/tree	Number of Injection Sites
4 to 6	15	25	50	-	3
7 to 9	20	40	80	-	4
10 to 12	30	55	110	165	5
13 to 15	35	70	140	210	6
16 to 18	42	85	170	255	7
19 to 21	50	100	200	300	8
22 to 24	-	115	230	345	10
25 to 27	-	130	260	390	11
28 to 30	-	145	290	435	12
31 to 33	-	160	320	480	13
34 to 36	-	175	350	525	15
37 to 39	-	190	380	570	16
40 to 42	-	205	410	615	17
43 to 45	-	220	440	660	18
46 to 48	-	235	470	705	20
49 to 51	-	250	500	750	21
52 to 54	-	265	530	795	22
55 to 57	-	280	560	840	23
58 to 60	-	295	590	885	25
61 to 63	-	310	620	930	26
64 to 66	-	325	650	975	27
67 to 69	-	340	680	1020	28
70 to 72	-	355	710	1065	30

The use of low, medium, medium high and high rates are based on the professional judgment of the applicator as to what constitutes a low, medium or high infestation.

Higher rates tend to provide longer residual and control of more difficult to control insects. See **Target Pest** for additional information in choosing the amount of product to apply.

Applications in Trees

Tree Tissue	Target Pest	Application Rate[1]	Comments
Seed and Cone	Pine Coneworm (*Dioryctria* spp) Pine Cone Seed Bug (suppression of *Leptoglossus* and *Tetyra* spp in the year of treatment)	Medium to High	For optimal control apply in the fall for early season pests or at least 30 days before insect attack.
Bud and Leaf	Tent Caterpillars (including Eastern, Forest, Pacific, and Western) Western Spruce Budworm Winter Moth	Low to Medium	Apply at least 2-3 weeks before the pest has historically been present. Consult with local extension agent for when this will occur in your area.
	Bagworm Fall Webworm Gypsy Moth Mimosa Webworm Oak Worm Tussock Moth Leafminers (including Lepidoptera, Coleoptera, Hymenoptera) Honeylocust Plant Bug Pine Needle Scale Red Palm Mite Sawfly (including Elm, Pine)	Low to High	
Shoot, Stem, Trunk and Branch	Clearwing Borers (including Ash, and Sequoia Pine Pitch Tube Moth)	Low to Medium	For control apply at least 30 days before historical egg hatch or adult flight and to trees whose vascular tissue is not damaged. If vascular tissue is damaged or plugged by insect galleries, nematodes or fungi, uniform treatment and control may not be achieved.
	Flat-headed Borers (including adult and larvae of Emerald Ash Borer)	Low to High	
	Roundheaded Borers (excluding Asian longhorn Borer) **Scolytids (bark beetles)** *Ips* Engraver Beetles Mountain Pine Beetle Southern Pine Beetle Spruce Beetle Western Pine Beetle Pinewood Nematode	Medium to High	

[1]Use medium to high rates for remedial and longer residual control.

Compatibility

Do not mix Emamectin Benzoate 4.0% Tree Injection before injection with other products such as insecticides, fungicides, plant growth regulators, surfactants, adjuvants, and fertilizers.

RESTRICTION

Do not apply to trees that may yield food consumed by humans or used in animal feed.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage

Store in a cool, dry place, away from children and pets. Keep from freezing.

Pesticide Disposal

Waste resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Handling

Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use and disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

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For non-emergency (e.g., current product information), call Syngenta Crop Protection at 1-800-334-9481.

Manufactured for:
Syngenta Crop Protection, LLC
P.O. Box 18300
Greensboro, North Carolina 27419-8300
SCP 1309A-M(draft rate)
EmaBenz Tree Injection 1309A-M(draft rate)marked-lg-1-4-11 **000100-01309.20110105.rate.pdf**

(Non-detachable container label)

RESTRICTED USE PESTICIDE
DUE TO ACUTE TOXICITY TO HUMANS
FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION, AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION.

Emamectin Benzoate 4.0% Tree Injection

Injected insecticide for the control of listed arthropod pests in deciduous, coniferous, and palm trees

Active Ingredient:	
Emamectin Benzoate[1]	4.0%
Other Ingredients:	96.0%
Total:	100.0%

[1]CAS No.155569-91-8
Contains 0.36 lbs. emamectin per gallon.

KEEP OUT OF REACH OF CHILDREN.

WARNING/AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

See additional precautionary statements and directions for use in booklet.

EPA Reg. No. 100-1309

EPA Est. xxxxx

SCP 1309A-M(draft rate)

_____
Net Contents

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING/AVISO

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear. Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID	
If in eyes	•Hold eye open and rinse slowly and gently with water for 15-20 minutes. •Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. •Call a poison control center or doctor for treatment advice.
If swallowed	•Call poison control center or doctor immediately for treatment advice. •Have person sip glass of water if able to swallow. •Do not induce vomiting unless told to do so by the poison control center or doctor. •Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN

Early signs of intoxication include dilation of pupils, muscular incoordination, and muscular tremors. Vomiting within one-half hour of exposure can minimize toxicity following accidental ingestion of the product; rapidly after exposure (< 15 minutes) administer repeatedly medical charcoal in a large quantity of water or ipecac. If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive parenteral fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels and proper respiratory functionality) as indicated by clinical signs, symptoms, and measurements. In severe cases, observations should continue for at least several days until clinical condition is stable and normal. Since emamectin benzoate is believed to enhance GABA activity in animals, it is probably wise to avoid drugs that enhance GABA activity (barbiturates, benzodiazepines, valproic acid) in patients with potentially toxic emamectin benzoate exposure.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
HOT LINE NUMBER For 24-Hour Medical Emergency Assistance (Human or Animal), Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident) Call **1-800-888-8372**

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage
Store in a cool, dry place, away from children and pets. Keep from freezing.

Pesticide Disposal
Waste resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Handling
Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use and disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

The Syngenta logo is a trademark of a Syngenta Group Company
©2011 Syngenta
Manufactured for:
Syngenta Crop Protection, LLC
P.O. Box 18300
Greensboro, North Carolina 27419-8300

SCP 1309A-M(draft rate)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 10, 2011

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

BUNNIE KONAT
SYNGENTA CROP PROTECTION, LLC
ATTN: REGULATORY AFFAIRS
PO Box 18300
GREENSBORO, NC 27419-8300

PRODUCT NAME: EMAMECTIN BENZOATE 4.0% TREE INJECTION
COMPANY NAME: SYNGENTA CROP PROTECTION, LLC
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 100-1309
EPA RECEIPT DATE: 01/07/11

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 7, at (703) 308-6249.

Sincerely,

P. K. Moore
Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

Fee for Service {888590E~

This package includes the following

- ○ New Registration
- ◉ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ○ AD
- ○ BPPD
- ◉ RD

Risk Mgr. 7

Receipt No. S- 888590

EPA File Symbol/Reg. No. 100-1309

Pin-Punch Date: 1/7/2011

☒ This item is NOT subject to FFS action.

Action Code:

Requested: ____

Granted: ____

Amount Due: $ _____

Parent/Child Decisions:

▣ Inert Cleared for Intended Use ▣ Uncleared Inert in Product

Reviewer: Shaunta Hill Date: 1/10/11

Remarks:

IRB-7

FAST-TRACK AMENDMENTS–Completeness Screening Checklist

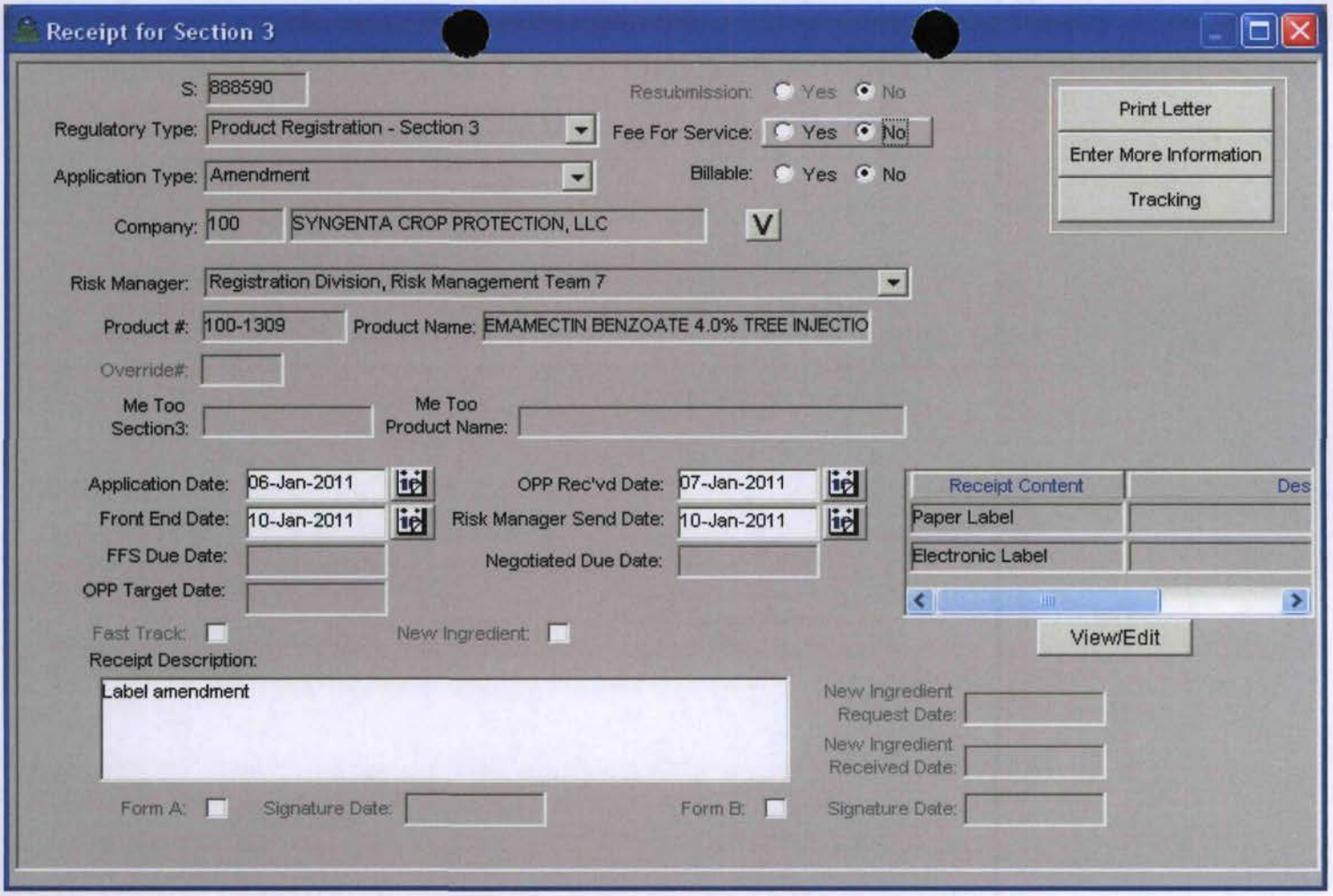
Experts In-Processing Signature: S. Hill

EPA Reg. Number: 100-1309	EPA Receipt Date: 1/7/11

	Check List Item	Yes	No	NA
1	**Application Form** (EPA Form 8570-1) –signed?	X		
2	**Confidential Statement of Formula** (EPA Form 8570-29) – signed?			X
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) signed?			X
4	**Formulator's Exemption Statement** (EPA Form 8570-27) - signed?			X
5	**Data Matrix** (EPA Form 8570-35) [Applicable, for adding me-too uses]			X
	a) Selective Method?			
	b) Cite-All Method? Applicant owns data or list only the companies offered to pay			
	c) Public copy of Matrix provided? See PR Notice 98-5			
6	**Is Label Included? (5 copies)** e-label avail	X		
	Comments:			

– Tom Harris

– 300 action code –


Receipt for Section 3
S: 888590
Resubmission: Yes No
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: Amendment
Billable: Yes No
Company: 100 SYNGENTA CROP PROTECTION, LLC
Print Letter
Enter More Information
Tracking
Risk Manager: Registration Division, Risk Management Team 7
Product #: 100-1309
Product Name: EMAMECTIN BENZOATE 4.0% TREE INJECTIO
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 06-Jan-2011
OPP Rec'vd Date: 07-Jan-2011
Front End Date: 10-Jan-2011
Risk Manager Send Date: 10-Jan-2011
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Des
Paper Label
Electronic Label
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
Label amendment
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

Thomas J. Parshley
Senior Regulatory Product Manager
Syngenta Regulatory Affairs
Lawn and Garden Products
(336) 632-7207 (phone)
(336) 632-5688 (fax)
tom.parshley@syngenta.com

Syngenta Crop Protection, LLC
P.O. Box 18300
Greensboro, NC 27419-8300
www.syngenta.com

syngenta

FedEx

January 6, 2011

Document Processing Desk (**AMEND**)
Office of Pesticide Programs (**7504P**)
U.S. Environmental Protection Agency
2777 South Crystal Drive
Room S-4900, One Potomac Yard
Arlington, VA 22202-4501

Attention: **Mr. Thomas Harris, Insecticide-Rodenticide Branch**
Registration Division

SUBJECT: ***AMENDMENT TO CORRECT ERRORS IN RATE TABLE***
EMAMECTIN BENZOATE 4% TREE INJECTION
EPA REG. NO. 100-1309

Dear Mr. Harris:

Enclosed please find the following information in support of the subject amendment request:

- Application for Pesticide Amendment, EPA Form 8570-1
- Five copies of revised product labeling (one copy highlighted to indicate changes)
- Label Certification Form and a compact disk (CD) that contains the highlighted revised product labeling

The purpose of this submission is to correct the rates for the 16-18 inch diameter trees. This required a slight change upward in the various rates for these diameter trees to align the rates with the other tree sizes. All other rates had been calculated correctly from the beginning. Please contact me at (336) 632-7207 if there are any questions concerning this submission. Thank you for your kind consideration of this request

Sincerely,

Thomas J Parshley

Thomas J. Parshley
NAFTA Senior Regulatory Product Manager
Syngenta Regulatory Affairs

Enclosures (forms, labeling, CD)

Please read instructions on reverse before completing form.

United States Environmental Protection Agency Washington, DC 20460	[ ] Registration [X] Amendment [ ] Other	OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
100-1309	Thomas Harris	[X] None [ ] Restricted
4. Company/Product (Name)	PM# 4B	
Emamectin Benzoate 4.0% Tree Injection	IRB	
5. Name and Address of Applicant *(Include ZIP Code)* Syngenta Crop Protection, LLC P. O. Box 18300 Greensboro, NC 27419 [ ] *Check if this is a new address*	6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

[X] Amendment - Explain below.

[ ] Resubmission in response to Agency letter dated _____

[ ] Notification - Explain below.

[ ] Final printed labels in response to Agency letter dated _____

[ ] "Me Too" Application.

[ ] Other - Explain below. New Product-nonfood use

Explanation: Use additional page(s) if necessary. (For Section I and Section II.).

Administrative amendment to correct errors on the rate tables for 16-18 inch diameter trees.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [x] No	[ ] Yes [x] No	[ ] Yes [x] No	[ ] Metal [x] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) Plastic tube
***Certification must**	If "Yes" Unit Packaging wgt. / No. per Container	If "Yes" Unit Packaging wgt. / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[x] Label [ ] Container	1 pint to 55 gallons	[x] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product: [ ] Lithograph [x] Paper glued for tubes [ ] Stenciled [ ] Outer box is preprinted _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Thomas J. Parshley	Senior Reg. Product Manager	336-632-7207

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received **(Stamped)**

2. Signature	3. Title
Thomas J Parshley	Senior Regulatory Product Manager
4. Typed Name: Thomas J. Parshley	5. Date: January 6, 2011

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.

Certification with Respect to Label Integrity

Version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL		
EPA Registration #	Date Submitted to EPA	Electronic file name
100-1309	January 5, 2011	000100-01309.20110105.rate.pdf

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

Thomas J Parshley

Signature

January 5, 2011

Date

Thomas J Parshley

Name (typed)

Sr. Regulatory Product Manager

Title

Material to be added to an e-Jacket/Jacket

Reg. # 100-1309 Decision # 427963

Description: expand sites & pests

1. Placement within the e-Jacket/jacket:
   - ☑ Default: (chronological, top = newest)
   - ☐ File Location: (eg. "before page 45 in .pdf")

2. ☑ Send to Data Extraction contractors this material:
   - ☑ Newly stamped accepted label
   - ☐ Notification
   - ☐ New CSF
   - ☐ Other: _____

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: Tom Harris Division: RD

Phone: 308-9423 Date: 12/16/10

Created December 6, 2010

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

12/20/2010

Tom Parshley
Syngenta Crop Protection, Inc.
PO Box 18300
Greensboro, NC 27419

Subject: Emamectin Benzoate 4.0% Tree Injection, EPA Reg. # 100-1309
reviews associated with label accepted 12/16/2010

Dear Mr. Parshley:

Enclosed please find a copy of the following review associated with the amendment to this product (expansion of sites and pests) accepted 12/16/2010.

Hurley, P. 12/1/2010. Section 3 Product Registration Request for Expansion of Tree Species for Emamectin Benzoate Tree Injection Use to Control Arthropod Pests.

Sincerely yours,

Thomas C. Harris
Insecticide / Rodenticide Branch
Registration Division (7505C)
Office of Pesticide Programs
harris.thomas@epa.gov
(703) 308-9423

enclosures (1)

Stamped label: Emamectin Tree Injection, # 100- 1309 expand tree species

Thomas Harris to: tom.parshley 12/16/2010 06:04 PM

Cc: carolyn.brinkley

Tom,

Attached is a stamped accepted label expanding the sites for 100-1309. I decided not to imposed the comment I had mention since I realized "burning" and "incineration" were two different concepts.

000100-01309.20101216.expand sites pests.amd.a.stamped label.pdf

This email will serve as the official transmission of this accepted label (unless you request a paper copy be sent). I'll send you e-copies of the reviews early next week.

Tom Harris
EPA/OCSPP/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

12/16/2010

Tom Parshley
Syngenta Crop Protection, Inc.
PO Box 18300
Greensboro, NC 27419

re: Emamectin Benzoate 4.0% Tree Injection, EPA Reg. # 100-1309
label amendment submitted 2/10/2010 (D#427963)
accepted with comments

Dear Mr. Parshley:

The revised labeling submitted in connection with the registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is ACCEPTABLE. This label amendment expands the sites and pests on the label.

Submit two (2) copies of your final printed labeling incorporating the above changes prior to releasing your product for shipment. If the above provisions are not complied with the registration will be subject to cancellation in accordance with FIFRA Section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A copy of the label stamped "accepted" is enclosed for your records. If you have any questions please contact Tom Harris at (703) 308-9423 or harris.thomas@epa.gov

Yours truly,

John Hebert
Product Manager (07)
Insecticide-Rodenticide Branch
Registration Division (7505P)

enclosure

(Master label)

RESTRICTED USE PESTICIDE
DUE TO ACUTE TOXICITY TO HUMANS
FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION, AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION.

Emamectin Benzoate 4.0% Tree Injection

Injected insecticide for two year control of listed arthropod pests in deciduous, coniferous, and palm trees

Active Ingredient:	
Emamectin Benzoate[1]	4.0%
Other Ingredients:	96.0%
Total:	100.0%

[1]CAS No.155569-91-8
Contains 0.36 lbs. emamectin per gallon.

KEEP OUT OF REACH OF CHILDREN.

WARNING/AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

See additional precautionary statements and directions for use on label[in booklet].

EPA Reg. No. 100-1309

EPA Est. xxxxx

Product of xxxxx
Formulated in xxxxx

SCP 1309A-M(draft)

ACCEPTED
DEC 16 2010
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under:

EPA. Reg. No: 100-1309

Net Contents

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING/AVISO

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear. Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID	
If in eyes	•Hold eye open and rinse slowly and gently with water for 15-20 minutes. •Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. •Call a poison control center or doctor for treatment advice.
If swallowed	•Call poison control center or doctor immediately for treatment advice. •Have person sip glass of water if able to swallow. •Do not induce vomiting unless told to do so by the poison control center or doctor. •Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN

Early signs of intoxication include dilation of pupils, muscular incoordination, and muscular tremors. Vomiting within one-half hour of exposure can minimize toxicity following accidental ingestion of the product; rapidly after exposure (< 15 minutes) administer repeatedly medical charcoal in a large quantity of water or ipecac. If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive parenteral fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels and proper respiratory functionality) as indicated by clinical signs, symptoms, and measurements. In severe cases, observations should continue for at least several days until clinical condition is stable and normal. Since emamectin benzoate is believed to enhance GABA activity in animals, it is probably wise to avoid drugs that enhance GABA activity (barbiturates, benzodiazepines, valproic acid) in patients with potentially toxic emamectin benzoate exposure.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
HOT LINE NUMBER For 24-Hour Medical Emergency Assistance (Human or Animal), Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident) Call **1-800-888-8372**

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Chemical–resistant gloves (Category C) such as barrier laminate; butyl rubber ≥14 mils; nitrile rubber ≥14 mils; or neoprene rubber ≥14 mils.
- Shoes and socks
- Protective eyewear

Environmental Hazards

This product is highly toxic to fish, mammals and aquatic invertebrates. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater. This product is highly toxic to bees exposed to direct treatment or residues on blooming trees.

Physical or Chemical Hazards

Do not use or store near heat or open flame.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, Inc. or Seller. To the extent permitted by applicable law, Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law: (1) this warranty does not extend to the use of the product contrary to label instructions or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and, (2) Buyer and User assume the risk of any such use. TO THE EXTENT PERMITTED BY APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.

DIRECTIONS FOR USE
RESTRICTED USE PESTICIDE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

IMPORTANT: Read entire label before using this product. Failure to follow label instructions may result in poor control or tree injury. Failure to follow label directions may cause injury to people, animals and environment.

APPLICATION TO TREES

Emamectin Benzoate 4.0% Tree Injection is for control of mature and immature arthropod pests of deciduous, coniferous, and palm trees, including, but not limited to, those growing in residential and commercial landscapes, parks, plantations, seed orchards, and forested sites (in private, municipal, state, tribal and national areas). Emamectin Benzoate 4.0% Tree Injection contains the active ingredient emamectin benzoate and is formulated to translocate in the tree's vascular system when injected. This product must be placed into active sapwood, and will actively control pests for up to two years.

USE DIRECTIONS

Emamectin Benzoate 4.0% Tree Injection is designed for use with tree injection devices that meet the label and dose requirements [(for example, the Arborjet Tree Injection Systems)] for the control of listed pests of trees. Follow manufacturer's directions for equipment use.

Dosages are based on the Diameter (in inches) of the tree at Breast Height (DBH"). Tree DBH is the outside bark diameter at breast height. Breast height is defined as 4.5 feet (1.37m) above the ground on the uphill side of the tree. For the purposes of determining breast height, the ground includes the duff layer that may be present, but does not include unincorporated woody debris that may rise above the ground line.

The diameter is determined by measuring the circumference of the tree at DBH", and dividing the circumference (in inches) by three (3). To determine DBH" for multi-stemmed woody ornamentals, measure the DBH" for each stem or branch and add together for the total DBH" per tree.

Placement of Application/Injection Sites: Inject at the base of the tree. Inject into the stem within 12" of the soil, into the trunk flare or into tree roots exposing them by shallow excavation. Make applications into intact, healthy sapwood. Do not inject into injured areas or areas with decay. Select injection sites associated with stem growth.

Number of Injection Sites: Work around the tree, spacing injection sites approximately every 6.0 inches of tree's circumference.

Drill Depth: Drill through the bark then 5/8" to 1-5/8" (hardwoods) or 1-5/8" to 2" (conifers) into the sapwood with the appropriate sized drill bit. Use clean, sharp drill bits. Brad point bits are recommended. Precautions should be taken to avoid diseased areas and transferring infected tissues to other injection sites.

Resinous Conifers

In resinous conifers, such as pine and spruce, start the injection immediately after drilling into the sapwood. A prolonged delay may reduce uptake on account of resin flow into opening.

WHEN TO TREAT

Emamectin Benzoate 4.0% Tree Injection contains the active ingredient emamectin benzoate which is a glycoside insecticide. It is active against immature and adult stages of arthropods. The primary route of toxicity is through ingestion.

ENVIRONMENTAL CONDITIONS: Uptake of Emamectin Benzoate 4.0% Tree Injection is dependent upon the tree's transpiration. Transpiration is dependent on a number of abiotic and biotic factors, such as soil moisture, soil and ambient temperature, and time of day. For uptake, apply when soil is moist, soil temperatures are above 45°F, ambient temperatures are between 40° to 90°F, and during the 24 hour period when transpiration is greatest, typically before 2:00 PM. Applications to drought or heat stressed trees may result in injury to tree tissue, poor treatment and subsequent control. Avoid treating trees that are moisture stressed or suffering from herbicide damage.

MONITOR TREE HEALTH and PEST INFESTATIONS: Effective injection treatment is favored by a full canopy (i.e., leaves) and healthy vascular system. Once these tissues are compromised by arthropod damage (larval galleries, defoliation, leaf mining, etc.) an effective and uniform application of Emamectin Benzoate 4.0% Tree Injection may be difficult to achieve and subsequent control may be poor. Optimally, treatment should be made preventively at least 2 to 3 weeks before arthropods historically infest the host tree. As a result of systemic movement and longevity of Emamectin Benzoate 4.0% Tree Injection in trees, this interval may be extended much earlier to 6 months should tree dormancy, adverse weather, management, asynchronous life cycle of pests, etc., allow earlier application timing.

Emamectin Benzoate 4.0% Tree Injection may also be effective as a remedial treatment against some pests, such as those with slower development or if multiple life stages are susceptible to Emamectin Benzoate 4.0% Tree Injection. Pests that attack the stem and branches such as bark beetles and clearwing borers may disrupt vascular tissue resulting in poor distribution in an infested tree. This includes the initial larval stages of pests, such as bark beetles and clearwing borers, that attack the stem and branches, which may disrupt vascular tissue resulting in poor distribution of the product in an

infested tree. However, control may be achieved if larvae come into contact or feed on Emamectin Benzoate 4.0% Tree Injection treated tissues.

USE

Use as formulated or dilute with equivalent 1 to 3 volumes of water or more, as necessary.

USE RATE TABLE

Tree Diameter (DBH) (Inches)	Low ml. product/tree	Medium ml. product/tree	Medium - High ml. product/tree	High ml. product/tree	Number of Injection Sites
4 to 6	15	25	50	-	3
7 to 9	20	40	80	-	4
10 to 12	30	55	110	165	5
13 to 15	35	70	140	210	6
16 to 18	40	75	150	225	7
19 to 21	50	100	200	300	8
22 to 24	-	115	230	345	10
25 to 27	-	130	260	390	11
28 to 30	-	145	290	435	12
31 to 33	-	160	320	480	13
34 to 36	-	175	350	525	15
37 to 39	-	190	380	570	16
40 to 42	-	205	410	615	17
43 to 45	-	220	440	660	18
46 to 48	-	235	470	705	20
49 to 51	-	250	500	750	21
52 to 54	-	265	530	795	22
55 to 57	-	280	560	840	23
58 to 60	-	295	590	885	25
61 to 63	-	310	620	930	26
64 to 66	-	325	650	975	27
67 to 69	-	340	680	1020	28
70 to 72	-	355	710	1065	30

The use of low, medium, medium high and high rates are based on the professional judgement of the applicator as to what constitutes a low, medium or high infestation.

Higher rates tend to provide longer residual and control of more difficult to control insects. See **Target Pest** for additional information in choosing the amount of product to apply.

Applications in Trees

Tree Tissue	Target Pest	Application Rate[1]	Comments
Seed and Cone	Pine Coneworm (*Dioryctria* spp) Pine Cone Seed Bug (suppression of *Leptoglossus* and *Tetyra* spp in the year of treatment)	Medium to High	For optimal control apply in the fall for early season pests or at least 30 days before insect attack.
Bud and Leaf	Tent Caterpillars (including Eastern, Forest, Pacific, and Western) Western Spruce Budworm Winter Moth	Low to Medium	Apply at least 2-3 weeks before the pest has historically been present. Consult with local extension agent for when this will occur in your area.
	Bagworm Fall Webworm Gypsy Moth Mimosa Webworm Oak Worm Tussock Moth Leafminers (including Lepidoptera, Coleoptera, Hymenoptera) Honeylocust Plant Bug Pine Needle Scale Red Palm Mite Sawfly (including Elm, Pine)	Low to High	
Shoot, Stem, Trunk and Branch	Clearwing Borers (including Ash, and Sequoia Pine Pitch Tube Moth)	Low to Medium	For control apply at least 30 days before historical egg hatch or adult flight and to trees whose vascular tissue is not damaged. If vascular tissue is damaged or plugged by insect galleries, nematodes or fungi, uniform treatment and control may not be achieved.
	Flat-headed Borers (including adult and larvae of Emerald Ash Borer)	Low to High	
	Roundheaded Borers (excluding Asian longhorn Borer) **Scolytids (bark beetles)** *Ips* Engraver Beetles Mountain Pine Beetle Southern Pine Beetle Spruce Beetle Western Pine Beetle Pinewood Nematode	Medium to High	

[1]Use medium to high rates for remedial and longer residual control.

Compatibility

Do not mix Emamectin Benzoate 4.0% Tree Injection before injection with other products such as insecticides, fungicides, plant growth regulators, surfactants, adjuvants, and fertilizers.

RESTRICTION

Do not apply to trees that may yield food consumed by humans or used in animal feed.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage

Store in a cool, dry place, away from children and pets. Keep from freezing.

Pesticide Disposal

Waste resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Handling

Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use and disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

The Syngenta logo and the CP FRAME are trademarks of a Syngenta Group Company
©2010 Syngenta

For non-emergency (e.g., current product information), call Syngenta Crop Protection at 1-800-334-9481.

Manufactured for:
Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, North Carolina 27419-8300
SCP 1309A-M(draft)
EmaBenz Tree Injection 1309A-M(draft)clean-lg-2-8-2010 000100-01309.20100210.pdf

(Non-detachable container label)

RESTRICTED USE PESTICIDE
DUE TO ACUTE TOXICITY TO HUMANS
FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION, AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION.

Emamectin Benzoate 4.0% Tree Injection

Injected insecticide for the control of listed arthropod pests in deciduous, coniferous, and palm trees

Active Ingredient:	
Emamectin Benzoate[1]	4.0%
Other Ingredients:	96.0%
Total:	100.0%

[1]CAS No.155569-91-8
Contains 0.36 lbs. emamectin per gallon.

KEEP OUT OF REACH OF CHILDREN.

WARNING/AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

See additional precautionary statements and directions for use in booklet.

EPA Reg. No. 100-1309

EPA Est. xxxxx

SCP 1309A-M(draft)

_____
Net Contents

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING/AVISO

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear. Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID	
If in eyes	•Hold eye open and rinse slowly and gently with water for 15-20 minutes. •Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. •Call a poison control center or doctor for treatment advice.
If swallowed	•Call poison control center or doctor immediately for treatment advice. •Have person sip glass of water if able to swallow. •Do not induce vomiting unless told to do so by the poison control center or doctor. •Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN

Early signs of intoxication include dilation of pupils, muscular incoordination, and muscular tremors. Vomiting within one-half hour of exposure can minimize toxicity following accidental ingestion of the product; rapidly after exposure (< 15 minutes) administer repeatedly medical charcoal in a large quantity of water or ipecac. If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive parenteral fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels and proper respiratory functionality) as indicated by clinical signs, symptoms, and measurements. In severe cases, observations should continue for at least several days until clinical condition is stable and normal. Since emamectin benzoate is believed to enhance GABA activity in animals, it is probably wise to avoid drugs that enhance GABA activity (barbiturates, benzodiazepines, valproic acid) in patients with potentially toxic emamectin benzoate exposure.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
HOT LINE NUMBER For 24-Hour Medical Emergency Assistance (Human or Animal), Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident) Call **1-800-888-8372**

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage
Store in a cool, dry place, away from children and pets. Keep from freezing.

Pesticide Disposal
Waste resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Handling
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The Syngenta logo and the CP FRAME are trademarks of a Syngenta Group Company
©2010 Syngenta
Manufactured for:
Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, North Carolina 27419-8300

SCP 1309A-M(draft)

Proposed 2/10/10 w/ changes

(Master label) mark-up

RESTRICTED USE PESTICIDE
DUE TO ACUTE TOXICITY TO HUMANS
FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION, AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION.

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See additional precautionary statements and directions for use on label[in booklet].

EPA Reg. No. 100-1309

EPA Est. xxxxx

Product of xxxxx
Formulated in xxxxx

SCP 1309A-M(draft)

Net Contents

DIRECTIONS FOR USE
RESTRICTED USE PESTICIDE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

IMPORTANT: Read entire label before using this product. Failure to follow label instructions may result in poor control or tree injury. Failure to follow label directions may cause injury to people, animals and environment.

APPLICATION TO TREES

Emamectin Benzoate 4.0% Tree Injection is for control of mature and immature arthropod pests of deciduous, coniferous, and palm trees, including, but not limited to, those growing in residential and commercial landscapes, parks, plantations, seed orchards, and forested sites (in private, municipal, state, tribal and national areas). Emamectin Benzoate 4.0% Tree Injection contains the active ingredient emamectin benzoate and is formulated to translocate in the tree's vascular system when injected. This product must be placed into active sapwood, and will actively control pests for up to two years.

USE DIRECTIONS

Emamectin Benzoate 4.0% Tree Injection is designed for use with tree injection devices that meet the label and dose requirements [(for example, the Arborjet Tree Injection Systems)] for the control of listed pests of trees. Follow manufacturer's directions for equipment use.

Dosages are based on the Diameter (in inches) of the tree at Breast Height (DBH"). Tree DBH is the outside bark diameter at breast height. Breast height is defined as 4.5 feet (1.37m) above the ground on the uphill side of the tree. For the purposes of determining breast height, the ground includes the duff layer that may be present, but does not include unincorporated woody debris that may rise above the ground line.

The diameter is determined by measuring the circumference of the tree at DBH", and dividing the circumference (in inches) by three (3). To determine DBH" for multi-stemmed woody ornamentals, measure the DBH" for each stem or branch and add together for the total DBH" per tree.

Placement of Application/Injection Sites: Inject at the base of the tree. Inject into the stem within 12" of the soil, into the trunk flare or into tree roots exposing them by shallow excavation. Make applications into intact, healthy sapwood. Do not inject into injured areas or areas with decay. Select injection sites associated with stem growth.

Number of Injection Sites: Work around the tree, spacing injection sites approximately every 6.0 inches of tree's circumference.

Drill Depth: Drill through the bark then 5/8" to 1-5/8" (hardwoods) or 1-5/8" to 2" (conifers) into the sapwood with the appropriate sized drill bit. Use clean, sharp drill bits. Brad point bits are recommended. Precautions should be taken to avoid diseased areas and transferring infected tissues to other injection sites.

Resinous Conifers

In resinous conifers, such as pine and spruce, start the injection immediately after drilling into the sapwood. A prolonged delay may reduce uptake on account of resin flow into opening.

WHEN TO TREAT

Emamectin Benzoate 4.0% Tree Injection contains the active ingredient emamectin benzoate which is a glycoside insecticide. It is active against immature and adult stages of arthropods. The primary route of toxicity is through ingestion.

ENVIRONMENTAL CONDITIONS: Uptake of Emamectin Benzoate 4.0% Tree Injection is dependent upon the tree's transpiration. Transpiration is dependent on a number of abiotic and biotic factors, such as soil moisture, soil and ambient temperature, and time of day. For uptake, apply when soil is moist, soil temperatures are above 45°F, ambient temperatures are between 40° to 90°F, and during the 24 hour period when transpiration is greatest, typically before 2:00 PM. Applications to drought or heat stressed trees may result in injury to tree tissue, poor treatment and subsequent control. Avoid treating trees that are moisture stressed or suffering from herbicide damage.

MONITOR TREE HEALTH and PEST INFESTATIONS: Effective injection treatment is favored by a full canopy (i.e., leaves) and healthy vascular system. Once these tissues are compromised by arthropod damage (larval galleries, defoliation, leaf mining, etc.) an effective and uniform application of Emamectin Benzoate 4.0% Tree Injection may be difficult to achieve and subsequent control may be poor. Optimally, treatment should be made preventively at least 2 to 3 weeks before arthropods historically infest the host tree. As a result of systemic movement and longevity of Emamectin Benzoate 4.0% Tree Injection in trees, this interval may be extended much earlier to 6 months should tree dormancy, adverse weather, management, asynchronous life cycle of pests, etc., allow earlier application timing.

Emamectin Benzoate 4.0% Tree Injection may also be effective as a remedial treatment against some pests, such as those with slower development or if multiple life stages are susceptible to Emamectin Benzoate 4.0% Tree Injection. Pests that attack the stem and branches such as bark beetles and clearwing borers may disrupt vascular tissue resulting in poor distribution in an infested tree. This includes the initial larval stages of pests, such as bark beetles and clearwing borers, that attack the stem and branches, which may disrupt vascular tissue resulting in poor distribution of the product in an

infested tree. However, control may be achieved if larvae come into contact or feed on Emamectin Benzoate 4.0% Tree Injection treated tissues.

USE

Use as formulated or dilute with equivalent 1 to 3 volumes of water or more, as necessary.

USE RATE TABLE

Tree Diameter (DBH) (Inches)	Low ml. product/tree	Medium ml. product/tree	Medium - High ml. product/tree	High ml. product/tree	Number of Injection Sites
4 to 6	15	25	50	-	3
7 to 9	20	40	80	-	4
10 to 12	30	55	110	165	5
13 to 15	35	70	140	210	6
16 to 18	40	75	150	225	7
19 to 21	50	100	200	300	8
22 to 24	-	115	230	345	10
25 to 27	-	130	260	390	11
28 to 30	-	145	290	435	12
31 to 33	-	160	320	480	13
34 to 36	-	175	350	525	15
37 to 39	-	190	380	570	16
40 to 42	-	205	410	615	17
43 to 45	-	220	440	660	18
46 to 48	-	235	470	705	20
49 to 51	-	250	500	750	21
52 to 54	-	265	530	795	22
55 to 57	-	280	560	840	23
58 to 60	-	295	590	885	25
61 to 63	-	310	620	930	26
64 to 66	-	325	650	975	27
67 to 69	-	340	680	1020	28
70 to 72	-	355	710	1065	30

The use of low, medium, medium high and high rates are based on the professional judgement of the applicator as to what constitutes a low, medium or high infestation.

Higher rates tend to provide longer residual and control of more difficult to control insects. See **Target Pest** for additional information in choosing the amount of product to apply.

Applications in Trees

Tree Tissue	Target Pest	Application Rate[1]	Comments
Seed and Cone	Pine Coneworm (*Dioryctria* spp) Pine Cone Seed Bug (suppression of *Leptoglossus* and *Tetyra* spp in the year of treatment)	Medium to High	For optimal control apply in the fall for early season pests or at least 30 days before insect attack.
Bud and Leaf	Tent Caterpillars (including Eastern, Forest, Pacific, and Western) Western Spruce Budworm Winter Moth	Low to Medium	Apply at least 2-3 weeks before the pest has historically been present. Consult with local extension agent for when this will occur in your area.
	Bagworm Fall Webworm Gypsy Moth Mimosa Webworm Oak Worm Tussock Moth Leafminers (including Lepidoptera, Coleoptera, Hymenoptera) Honeylocust Plant Bug Pine Needle Scale Red Palm Mite Sawfly (including Elm, Pine)	Low to High	
Shoot, Stem, Trunk and Branch	Clearwing Borers (including Ash and Sequoia Pine Pitch Tube Moth)	Low to Medium	For control apply at least 30 days before historical egg hatch or adult flight and to trees whose vascular tissue is not damaged. If vascular tissue is damaged or plugged by insect galleries, nematodes or fungi, uniform treatment and control may not be achieved.
	Flat-headed Borers (including adult and larvae of Emerald Ash Borer)	Low to High	
	Roundheaded Borers (excluding Asian longhorn Borer) **Scolytids (bark beetles)** *Ips* Engraver Beetles Mountain Pine Beetle Southern Pine Beetle Spruce Beetle Western Pine Beetle Pinewood Nematode	Medium to High	

[1]Use medium to high rates for remedial and longer residual control.

mites are missing

Compatibility

Do not mix Emamectin Benzoate 4.0% Tree Injection before injection with other products such as insecticides, fungicides, plant growth regulators, surfactants, adjuvants, and fertilizers.

RESTRICTION

Do not apply to trees that may yield food ~~within 2 years of treatment~~ consumed by humans or used in animal feed.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage

Store in a cool, dry place, away from children and pets. Keep from freezing.

Pesticide Disposal

Waste resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Handling

Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use and disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

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For non-emergency (e.g., current product information), call Syngenta Crop Protection at 1-800-334-9481.

Manufactured for:
Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, North Carolina 27419-8300
SCP 1309A-M(draft)
EmaBenz Tree Injection 1309A-M(draft)clean-lg-2-8-2010 000100-01309 20100210.pdf

(Non-detachable container label)

RESTRICTED USE PESTICIDE
DUE TO ACUTE TOXICITY TO HUMANS
FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION, AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION.

Emamectin Benzoate 4.0% Tree Injection

Injected insecticide for the control of listed arthropod pests in deciduous, coniferous, and palm trees

Active Ingredient:	
Emamectin Benzoate[1]	4.0%
Other Ingredients:	96.0%
Total:	100.0%

[1]CAS No.155569-91-8
Contains 0.36 lbs. emamectin per gallon.

KEEP OUT OF REACH OF CHILDREN.

WARNING/AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

See additional precautionary statements and directions for use in booklet.

EPA Reg. No. 100-1309

EPA Est. xxxxx

SCP 1309A-M(draft)

_____
Net Contents

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
HOT LINE NUMBER For 24-Hour Medical Emergency Assistance (Human or Animal), Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident) Call **1-800-888-8372**

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage
Store in a cool, dry place, away from children and pets. Keep from freezing.

Pesticide Disposal
Waste resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Handling
Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use and disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by ~~incineration~~ – suggest delete or add back if allowed & stay out of smoke

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SCP 1309A-M(draft)

EmaBenz Tree Injection 1309A-M(draft)clean-lg-2-8-2010 000100-01309.20100210.pdf

(Master label)

RESTRICTED USE PESTICIDE
DUE TO ACUTE TOXICITY TO HUMANS
FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION, AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION.

Emamectin Benzoate 4.0% Tree Injection

Injected insecticide for two year control of listed arthropod pests in ~~ash trees (*Fraxinus* spp.)~~

Active Ingredient:	
Emamectin Benzoate[1]	4.0%
Other Ingredients:	96.0%
Total:	100.0%

[1]CAS No.155569-91-8
Contains 0.36 lbs. emamectin per gallon.

KEEP OUT OF REACH OF CHILDREN.

WARNING/AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

See additional precautionary statements and directions for use on label[in booklet].

EPA Reg. No. 100-1309

EPA Est. xxxxx

Product of xxxxx
Formulated in xxxxx

SCP 1309A-M(draft)

Net Contents

DIRECTIONS FOR USE
RESTRICTED USE PESTICIDE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

IMPORTANT: Read entire label before using this product. Failure to follow label instructions may result in poor control or tree injury. Failure to follow label directions may cause injury to people, animals and environment.

APPLICATION TO TREES

Emamectin Benzoate 4.0% Tree Injection is for control of mature and immature arthropod pests of ~~ash trees (*Fraxinus* spp.)~~, including, but not limited to, those growing in residential and commercial landscapes, parks, plantations, seed orchards, and forested sites (in private, municipal, state, tribal and national areas). Emamectin Benzoate 4.0% Tree Injection contains the active ingredient emamectin benzoate and is formulated to translocate in the tree's vascular system when injected. This product must be placed into active sapwood, and will actively control pests for up to two years.

USE DIRECTIONS

Emamectin Benzoate 4.0% Tree Injection is designed for use with tree injection devices that meet the label and dose requirements [(for example, the Arborjet Tree Injection Systems)] for the control of listed pests of trees. Follow manufacturer's directions for equipment use.

Dosages are based on the Diameter (in inches) of the tree at Breast Height (DBH"). Tree DBH is the outside bark diameter at breast height. Breast height is defined as 4.5 feet (1.37m) above the ground on the uphill side of the tree. For the purposes of determining breast height, the ground includes the duff layer that may be present, but does not include unincorporated woody debris that may rise above the ground line.

The diameter is determined by measuring the circumference of the tree at DBH", and dividing the circumference (in inches) by three (3). To determine DBH" for multi-stemmed woody ornamentals, measure the DBH" for each stem or branch and add together for the total DBH" per tree.

Placement of Application/Injection Sites: Inject at the base of the tree. Inject into the stem within 12" of the soil, into the trunk flare or into tree roots exposing them by shallow excavation. Make applications into intact, healthy sapwood. Do not inject into injured areas or areas with decay. Select injection sites associated with stem growth.

Number of Injection Sites: Work around the tree, spacing injection sites approximately every 6.0 inches of tree's circumference.

Drill Depth: Drill through the bark then 5/8" to ~~1-5/8" (ash trees)~~ into the sapwood with the appropriate sized drill bit. Use clean, sharp drill bits. Brad point bits are recommended. Precautions should be taken to avoid diseased areas and transferring infected tissues to other injection sites.

WHEN TO TREAT

Emamectin Benzoate 4.0% Tree Injection contains the active ingredient emamectin benzoate which is a glycoside insecticide. It is active against immature and adult stages of arthropods. The primary route of toxicity is through ingestion.

ENVIRONMENTAL CONDITIONS: Uptake of Emamectin Benzoate 4.0% Tree Injection is dependent upon the tree's transpiration. Transpiration is dependent on a number of abiotic and biotic factors, such as soil moisture, soil and ambient temperature, and time of day. For uptake, apply when soil is moist, soil temperatures are above 45˚F, ambient temperatures are between 40˚ to 90˚F, and during the 24 hour period when transpiration is greatest, typically before 2:00 PM. Applications to drought or heat stressed trees may result in injury to tree tissue, poor treatment and subsequent control. Avoid treating trees that are moisture stressed or suffering from herbicide damage.

MONITOR TREE HEALTH and PEST INFESTATIONS: Effective injection treatment is favored by a full canopy (i.e., leaves) and healthy vascular system. Once these tissues are compromised by arthropod damage (larval galleries, defoliation, leaf mining, etc.) an effective and uniform application of Emamectin Benzoate 4.0% Tree Injection may be difficult to achieve and subsequent control may be poor. Optimally, treatment should be made preventively at least 2 to 3 weeks before arthropods historically infest the host tree. As a result of systemic movement and longevity of Emamectin Benzoate 4.0% Tree Injection in trees, this interval may be extended much earlier to 6 months should tree dormancy, adverse weather, management, asynchronous life cycle of pests, etc., allow earlier application timing.

Emamectin Benzoate 4.0% Tree Injection may also be effective as a remedial treatment against some pests, such as those with slower development or if multiple life stages are susceptible to Emamectin Benzoate 4.0% Tree Injection. Pests that attack the stem and branches such as bark beetles and clearwing borers may disrupt vascular tissue resulting in poor distribution in an infested tree. This includes the initial larval stages of pests, such as bark beetles and clearwing borers, that attack the stem and branches, which may disrupt vascular tissue resulting in poor distribution of the product in an infested tree. However, control may be achieved if larvae come into contact or feed on Emamectin Benzoate 4.0% Tree Injection treated tissues.

USE

Use as formulated or dilute with equivalent 1 to 3 volumes of water or more, as necessary.

USE RATE TABLE

Tree Diameter (DBH) (Inches)	Low ml. product/tree	Medium ml. product/tree	Medium - High ml. product/tree	High ml. product/tree	Number of Injection Sites
4 to 6	15	25	50	-	3
7 to 9	20	40	80	-	4
10 to 12	30	55	110	165	5
13 to 15	35	70	140	210	6
16 to 18	40	75	150	225	7
19 to 21	50	100	200	300	8
22 to 24	-	115	230	345	10
25 to 27	-	130	260	390	11
28 to 30	-	145	290	435	12
31 to 33	-	160	320	480	13
34 to 36	-	175	350	525	15
37 to 39	-	190	380	570	16
40 to 42	-	205	410	615	17
43 to 45	-	220	440	660	18
46 to 48	-	235	470	705	20
49 to 51	-	250	500	750	21
52 to 54	-	265	530	795	22
55 to 57	-	280	560	840	23
58 to 60	-	295	590	885	25
61 to 63	-	310	620	930	26
64 to 66	-	325	650	975	27
67 to 69	-	340	680	1020	28
70 to 72	-	355	710	1065	30

The use of low, medium, medium high and high rates are based on the professional judgement of the applicator as to what constitutes a low, medium or high infestation.

Higher rates tend to provide longer residual and control of more difficult to control insects. See **Target Pest** for additional information in choosing the amount of product to apply.

Applications in Trees

Tree Tissue	Target Pest	Application Rate[1]	Comments
Bud and Leaf	Bagworm Fall Webworm Gypsy Moth Leafminers (including Diptera, Lepidoptera, Coleoptera, Hymenoptera) Orange-striped Oakworm	Low to High	Apply at least 2-3 weeks before the pest has historically been present. Consult with local extension agent for when this will occur in your area.
	Mites: Eriophid mites European red mite Spruce spider mites Twospotted spider mite Sawfly Erythrina gall wasp	Low to High	
	Tent Caterpillars (including Eastern, Forest, Pacific, and Western) Western Spruce budworm Winter Moth	Low to Medium	
Shoot, Stem, Trunk and Branch	**Buprestid Borers** (Flathead borers including Emerald Ash Borer, Bronze birch borer, two-lined chestnut borer)	Low to High	For control apply at least 30 days before historical egg hatch or adult flight and to trees whose vascular tissue is not damaged. If vascular tissue is damaged or plugged by insect galleries, nematodes or fungi, uniform treatment and control may not be achieved.
	Clearwing borers Horntails	Low to Medium	
	Longhorn borers (Roundhead borers including Eucalyptus, Pine Sawyer; excluding Asian longhorn beetles) Pine wood nematode Pales Weevil (*Hylobius pales*) **Scolytids (bark beetles)** *Ips* engraver beetles Mountain pine beetle Southern pine beetle Spruce beetle Western pine beetle White pine weevil	Medium to High	

[1]Use medium to high rates for remedial and longer residual control.

Compatibility

Do not mix Emamectin Benzoate 4.0% Tree Injection before injection with other products such as insecticides, fungicides, plant growth regulators, surfactants, adjuvants, and fertilizers.

RESTRICTION

~~This product is to be applied to ash trees only.~~ Do not apply to trees that may yield food consumed by humans or used in animal feed.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage

Store in a cool, dry place, away from children and pets. Keep from freezing.

Pesticide Disposal

Waste resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Handling

Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use and disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by ~~incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.~~

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SCP 1309A-M(draft)

TREE agc 1309A-M(draft)clean-lg 3-24-10 000100-01309.20100324.pdf

(Non-detachable container label)

RESTRICTED USE PESTICIDE
DUE TO ACUTE TOXICITY TO HUMANS
FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION, AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION.

Emamectin Benzoate 4.0% Tree Injection

Injected insecticide for the control of listed arthropod pests in ~~ash trees (*Fraxinus* spp.)~~

Active Ingredient:	
Emamectin Benzoate[1]	4.0%
Other Ingredients:	96.0%
Total:	100.0%

[1]CAS No.155569-91-8
Contains 0.36 lbs. emamectin per gallon.

KEEP OUT OF REACH OF CHILDREN.

WARNING/AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

See additional precautionary statements and directions for use in booklet.

EPA Reg. No. 100-1309

EPA Est. xxxxx

SCP 1309A-M(draft)

Net Contents

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
HOT LINE NUMBER For 24-Hour Medical Emergency Assistance (Human or Animal), Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident) Call **1-800-888-8372**

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage
Store in a cool, dry place, away from children and pets. Keep from freezing.

Pesticide Disposal
Waste resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Handling
Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use and disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by ~~incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.~~

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~~TREE-age 1309A-M(draft) clean-lg-3-24-10~~ ~~000100-01309.20100324.pdf~~

Text Comparison

Documents Compared

000100-01309.20100324 .pdf

000100-01309.20100210.pdf

Summary

252 word(s) added

219 word(s) deleted

3272 word(s) matched

19 block(s) matched

To see where the changes are, scroll down.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

December 1, 2010

PC Code: 122806
DP Barcode: 381025
MRID: 48257501
DECISION: 427963

MEMORANDUM

Subject: Section 3 Product Registration Request for Expansion of Tree Species for Emamectin Benzoate Tree Injection Use to Control Arthropod Pests

To: Thomas Harris
Insecticide/Rodenticide Branch
Registration Division

From: Pamela Hurley, Toxicologist Pamela J Hurley 11/30/2010
Dana Spatz, Chief 12-2-10
Environmental Risk Branch 3
Environmental Fate and Effects Division
Office of Pesticide Programs

Attached please find the Environmental Fate and Effects Division's (EFED) response to the request for additional tree species to the use of emamectin benzoate as a tree injection insecticide to control arthropod pests.

Background:

Syngenta submitted a request to expand the tree species for emamectin benzoate 4.0% tree injection (TREEäge™). The currently approved label is for two year control of selected arthropod pests in ash trees. The proposed label is for arthropod pests in deciduous, coniferous and palm trees, including, but not limited to, those growing in residential and commercial landscapes, parks, plantations, seed orchards, and forested sites. The pests listed on the label attack seed and cone; bud and leaf and shoot, stem, truck and branch. Emamectin benzoate is a restricted use pesticide. Due to acute toxicity to humans, it is proposed for retail sale to and use only by certified applicators or persons directly under their supervision.

The original risk assessment for this use (Appendix I: B. Anderson to T. Harris, dated 1/13/09; D351736), describes in detail the prior registrations for emamectin benzoate and the proposed tree injection process, including the application rate. The key findings of the original risk assessment for this use (Appendix I) included the following points:

"There is no standard methodology currently used by EFED to evaluate potential ecological risks from tree injection of insecticides. However, this screening level risk assessment identified potential risks to terrestrial invertebrates that forage on treated trees. Potential risks to birds, mammals, and terrestrial invertebrates also presumably exceed levels of concern, and potential risks to aquatic invertebrates could not be precluded.

Risk estimates were based on screening-level estimates of exposure. Submission of a study that measures the fate, uptake and translocation (magnitude of residues study) of emamectin benzoate in trees after injection would allow for a refined estimate of exposure and would be of high value to this risk assessment. This type of study requires submission of a formal protocol prior to study initiation and should include an evaluation of the magnitude of residues in edible parts of treated trees, including leaves, nectar, fruit, seeds, and pollen. Without submission of a study to allow for a refined estimation of potential exposures and risks to non-target animals, evaluating the effectiveness of potential mitigation options is not possible. In addition, submission of an acute oral LD_{50} study in bees would be of high value to this assessment.

Label statements that restrict the timing of application of emamectin benzoate and the type of tree that may be treated may be effective in limiting potential risks to non-target organisms. Such label statements may be developed after submission of the magnitude of residues study and would need to be vetted through EFED, RD, and the [Pollinator Protection Team]. Without submission of such a study, label statements similar to those recently developed for several neonicotinoid insecticides may be adapted."

In response to the request for a magnitude of residues study of emamectin benzoate in trees following injection, the Registrant submitted summary data on cherry (*Prunus avium*) pollen residues following injection of the emamectin benzoate formulation, Tree-Age® along with the analytical methods used to determine residues of emamectin benzoate in tree parts (MRID Nos. 47979301, 47767401, 48170001 and 48170002). In addition, literature articles on pollen selection by honey bees were submitted. The cherry summary data were informally reviewed by the Health Effects Division (HED) in order to determine whether or not it is sufficient for use in an ecological risk assessment. HED has received all the required documentation and has responded that the study may be used for the ecological assessment of risk.

The Registrant also submitted an acute oral toxicity study on honeybees (MRID 48257501) conducted with a 5% formulation and was used in their assessment of risk to honeybees. Review of that data has been completed and is deemed acceptable for a formulation.

Finally, the Registrant submitted a risk assessment for honeybees, based on the acute oral toxicity study and the cherry tree residue data (MRID 47979301). The Registrant estimated the potential acute risk to honey bees by comparing the Estimated Environmental Concentration (EEC) with the acute honey bee oral LD_{50} of the emamectin benzoate formulation on an active ingredient (a.i.) basis (6.8 ng/bee). For chronic exposure, they compared the EEC with the acute oral $LD_{50}/10$. The EEC was estimated by using the highest residue of emamectin benzoate detected in cherry tree pollen (9.2 µg/kg pollen) and the amount of pollen a honeybee would likely consume in one day (6.5 mg pollen/day for nurse bees). Assuming that the diet consisted exclusively of pollen, then the honey bee would potentially be exposed to 0.06 ng/day emamectin benzoate. Although for new use assessments the Agency has not developed a method to quantitatively assess risk to terrestrial invertebrates, for acute exposure, the Registrant then used a conservative Level of Concern (LOC) for endangered species (0.05) and compared it to the value obtained by dividing the EEC by the LD_{50}. The EEC of 0.06 ng/bee divided by the LD_{50} of 6.8 ng/bee is rounded to an estimate of 0.01. This estimate is 5 times below the LOC of 0.05.

For potential risk following chronic exposure, they assumed that the $LD_{50}/10$ could be used as a reasonably conservative estimate of a chronic toxicity NOAEL value. This estimation was based on a research project in which the author compared acute and non-guideline chronic toxicity studies on honeybees for 7 selected pesticides (Thompson H. 2007). This paper has not been submitted to the Agency. The $LD_{50}/10$ value was then compared to the EEC and an LOC of 1 for chronic exposure. The LD_{50} value of 6.8 ng/bee divided by ten is 0.68 ng/bee/day and the chronic exposure value was a conservative 0.06 ng/bee/day. The exposure value of 0.06 ng/bee/day divided by the toxicity value of 0.68 ng/bee/day is 0.09, which is 100 times lower than the chronic LOC of 1.

Agency Response:

Based on the acute oral toxicity study on honey bees and the cherry tree residue data that the Registrant has provided, the Agency agrees that the use of emamectin benzoate for tree injection is not likely to be a potential risk to foraging honey bees following acute exposure. However, due to lack of toxicity and exposure data, there are major uncertainties associated with potential risk to the brood and risk following chronic exposure.

It appears that with the restricted use and the method of application, this chemical may be used only for a limited number of high value trees as a preventative measure. If this is the case, then the overall risk to honey bees may be limited. Knowledge of the potential usage pattern for this product could significantly reduce the uncertainties associated with the overall risk to the honeybee population in the areas where this product will be used.

The following points list some of the uncertainties associated with the risks from this proposed use:

- There are insufficient data to assess either acute or chronic risk to bee larvae. Larvae may be more sensitive than the adults. In addition, they will also be exposed to nectar and other parts of the tree (resin (propolis)) used for nest construction. Residue data for parts of the tree other than pollen are not available [note: residue data for other parts of the tree would also be of use in assessment of risk to mammals and birds].
- There are insufficient data to assess risk following chronic exposure. The label states that the product is efficacious for 2 years. The product is designed to be a systemic pesticide. After it is injected into a tree, it is translocated throughout the tree via the sap. Therefore, chronic exposure is likely from all parts of the tree and again, neither residue data for parts of the tree other than pollen nor residue decline data are available. In addition, the Agency does not have access to the Thompson study (2007). Therefore, it is unclear what endpoints were evaluated for chronic toxicity to derive the acute-to-chronic ratio of 10.
- The acute oral toxicity study conducted on honey bees was with a 5% formulation. It is not known how the presence of the inerts will affect the toxicity of the test chemical. However, a comparison between the acute contact studies conducted with the same formulation and with the technical material indicates that the acute LD_{50}'s may not be substantially different between the formulation and the technical material on an a.i. basis.
- The studies of residues in pollen appear to focus on the parent compound alone and do not account for possible degradates. There were good recoveries of lab spikes (~102%) implying that degradation was not an issue in the lab; however, there are no field data to verify what happens in the field.
- There are no field spikes to monitor storage stability. Laboratory spikes using TGAI are reported, but no field spikes with the end-use product are reported.
- Cherry trees were treated in late January but were not sampled until early to mid-April. It is unclear whether or not this is the typical recommended tree injection process and what would be the expected profile of residues over time.
- The comparison to cherry tree treatments to loblolly pine treatments does not appear equivalent given that the pines are treated in April closer to the time they may be shedding pollen. The claims regarding the likely higher loading rate in cherry trees compared to pine presumes that residues are uniformly distributed throughout the volume of the plant. It is unclear as to whether or not this is the case.
- Pines may be anemophilus (wind-pollinated). The presumption that wind-pollinated plants are not attractive to bees is not entirely accurate. Corn is wind-pollinated and honeybees work corn for pollen.

Reference Cited by Registrant:

Thompson H. 2007. Assessment of the risk posed to honeybees by systemic pesticides. DEFRA Research Project PS2322 (not available to the Agency).

APPENDIX I

ORIGINAL RISK ASSESSMENT ON LABEL EXPANSION FOR TREE INJECTION USE

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

January 13, 2009

PC Code: 122806
DP Barcode: 351736

MEMORANDUM

Subject: Ecological risk assessment for emamectin benzoate use as a tree injection insecticide to control arthropod pests

To: Thomas Harris
Insecticide/Rodenticide Branch
Registration Division

From: Brian Anderson, Biologist
James Hetrick, Ph. D., Sr. Scientist
Paige Doelling, Ph. D., Acting Risk Assessment Process Leader
Dana Spatz, Chief
Environmental Risk Branch 3
Environmental Fate and Effects Division
Office of Pesticide Programs

Attached please find the Environmental Fate and Effects Division's (EFED) environmental risk assessment for the proposed new use of emamectin benzoate as a tree injection insecticide to control arthropod pests. Key findings of this risk assessment are as follows.

There is no standard methodology currently used by EFED to evaluate potential ecological risks from tree injection of insecticides. However, this screening level risk assessment identified potential risks to terrestrial invertebrates that forage on treated trees. Potential risks to birds, mammals, and terrestrial invertebrates also presumably exceed levels of concern, and potential risks to aquatic invertebrates could not be precluded.

Risk estimates were based on screening-level estimates of exposure. Submission of a study that measures the fate, uptake and translocation (magnitude of residues study) of

emamectin benzoate in trees after injection would allow for a refined estimate of exposure and would be of high value to this risk assessment. This type of study requires submission of a formal protocol prior to study initiation and should include an evaluation of the magnitude of residues in edible parts of treated trees, including leaves, nectar, fruit, seeds, and pollen. Without submission of a study to allow for a refined estimation of potential exposures and risks to non-target animals, evaluating the effectiveness of potential mitigation options is not possible. In addition, submission of an acute oral LD50 study in bees would be of high value to this assessment.

Data gaps noted in previous assessment (DP 309154) included the following (see the previous assessment for details):

- acute and chronic studies in sediment dwelling organisms (emamectin benzoate is expected to partition to and persist in sediment);
- acceptable life-cycle study in mysid shrimp;
- more sensitive analytical detection methodology;
- terrestrial plant toxicity data; and
- degradate toxicity data.

Neither studies nor acceptable data waivers have been submitted since the last assessment to satisfy these data gaps.

Label statements that restrict the timing of application of emamectin benzoate and the type of tree that may be treated may be effective in limiting potential risks to non-target organisms. Such label statements may be developed after submission of the magnitude of residues study and would need to be vetted through EFED, RD, and the pollinators team. Without submission of such a study, label statements similar to those recently developed for several neonicotinoid insecticides may be adapted.

The label was unclear with respect to application directions. For example, the label states that optimum control occurs if emamectin benzoate is applied at the base of the tree; however, application may also be made around the stem within 12 inches of the soil, in the trunk flare, or into tree roots. It is unclear, however, how the label directions can be followed for injection into the tree roots. Also, the amount of chemical to be added to each hole is not specified, and the label does not include any language to prevent or minimize spillage. If the holes drilled into the tree are filled until chemical spills out, then the potential for exposure to non-target organisms outside of the treated tree increases.

The label directions were also unclear with respect to application rates. Recommended application rates given on page 7 of the label were given in volume applied per tree. However, the label did not specify whether the application rate referred to volume of formulation or a.i. This assessment assumed that application rates referred to formulated product; however, the label should specify formulation or a.i.

EPA
United States
Environmental Protection
Agency

Office of Prevention, Pesticides,
and Toxic Substances

Section 3 Request for a New Use of the Insecticide Emamectin Benzoate (PC Code 122806)

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January 13, 2009

Table of Contents

1. Executive Summary

An ecological risk assessment was conducted that evaluated the proposed use of emamectin benzoate to control arthropod pests in trees. The proposed uses include residential and commercial landscapes, parks, plantations, seed orchards, and forested sites. The label does not limit the type of tree that may be treated or the pest that may be controlled other than arthropods, although a number of target pests are included on the label. Also, the label indicates that pests may be controlled in multiple parts of trees including the seed, cone, bud, leaf, shoot, stem, trunk, and branch.

The proposed application method is tree injection at a rate of approximately 15 mL to 1060 mL of product per tree (approximately 600 mg to 42,000 mg a.i./tree) (see Table 2.2 in Section 2). The amount of chemical applied depends on the size of the tree.

After emamectin benzoate is injected into a tree, it is translocated throughout the tree by the sap. There is currently not an approved model or standard methodology that allows for an estimation of exposure to a pesticide resulting from tree injection. This assessment used screening level estimates of exposure to evaluate potential risks and the value of additional data to refine potential exposures and risks. Submission of a study that measures the fate, uptake and translocation (magnitude of residue study) of emamectin benzoate in trees after injection to allow for an estimation of exposure to terrestrial animals is of high value to this assessment. This type of study requires submission of a formal protocol prior to study initiation and should include data on the magnitude of residues in leaves, pollen, and nectar. Because such a study is currently not available, the risk estimates included in this assessment are screening level estimates of risk.

Risk estimates were derived that were based on (1) the total mass of emamectin benzoate applied to a tree, (2) estimated concentrations of emamectin benzoate in leaves assuming 100% translocation of the pesticide to the leaves, and (3) estimated concentration of emamectin benzoate in the whole tree assuming that the pesticide is evenly distributed throughout the tree. Each of these screens resulted in risk concern for birds, mammals, and terrestrial invertebrates.

In addition, if emamectin benzoate is translocated primarily to leaves, then the chemical could enter the soil and be available for runoff into aquatic environments when the leaves fall to the ground. The amount of chemical that could enter the soil and water is related to the number and type of trees that are treated in a given area and the amount of chemical in the leaves. Screening methods using conservative assumptions could not preclude potential risks to aquatic invertebrates resulting from emamectin benzoate entering aquatic systems resulting from tree injection as described in Section 5.

2. Problem Formulation

2.1. Proposed Action

The registrant is requesting a new use for emamectin benzoate as an insecticide for control of arthropod pests on ornamental trees. The proposed application method is injection in trees located in residential and commercial landscapes, parks, plantations, seed orchards, and forested sites. The label does not limit the type of tree that may be treated or the pest that may be controlled other than arthropods, although a number of target pests are included on the label. Also, the label indicates that pests may be controlled in multiple parts of tree including the seed, cone, bud, leaf, shoot, stem, trunk, and branch.

2.2. Chemical Class and Mode of Action

Emamectin benzoate (Proclaim™) is an avermectin class insecticide developed for the control of lepidopteron insects. This class of pesticide consists of homologous semi-synthetic macrolides that are derived from the natural fermentation products of *Streptomyces* bacteria. It kills insects by disrupting neurotransmitters, causing irreversible paralysis. It is more effective when ingested, but it also somewhat effective on contact. Target pests are numerous. For the proposed use in tree injection, the target pests include mature and immature arthropod pests. It is lethal upon ingestion or direct contact.

When sprayed to foliage, emamectin benzoate penetrates the leaf tissue and forms a reservoir within treated leaves, which provides residual activity against foliage-feeding pests that ingest the substance when feeding. The proposed formulation is designed to translocate in the tree's vascular system when injected.

2.3. Pesticide Properties

The structure of emamectin benzoate is in Figure 2.1. Selected chemical and physical properties of emamectin benzoate are presented in Table 2.1. These data were obtained from a previous assessment (New Chemical Review, D226628), and studies from which these values were obtained were not re-evaluated. Emamectin benzoate consists of a mixture of at least 90% 4"-epi-methylamino-4"-deoxyavermectin B_{1a} and a maximum of 10% 4"-epi-methylamino-4"-deoxyavermectin B_{1b} benzoate. The available chemical properties and environmental fate data are primarily on the B_{1a} component; therefore, there is some uncertainty on the fate of the B_{1b} component. However, both components have very similar structures; therefore, their physicochemical properties, fate, and toxicity profiles are assumed to be similar. Some of emamectin benzoate's properties are pH dependent. For example, its water solubility is 320 mg/L at pH 5, 93 mg/L at pH 7, and 0.1 mg/L at pH 9. Similarly, its log Kow is 5.0 at pH 7 and 5.9 at pH 9. Therefore,

its properties may be altered by pH. Emamectin benzoate's low vapor pressure and Henry's law constant suggest that volatility from soil and water, respectively, will be low.

Table 2.1. Physical, Chemical, and Environmental Fate Properties of Emamectin Benzoate		
Property	**Value**	**Reference**
Molecular Weight	964	New Chemical Review (D226628, 2000)
CAS number	148477-71-8	New Chemical Review (D226628, 2000)
Water solubility; (pH 7)	93 mg/L	Product Chemistry; MRID 44883704;
Vapor pressure	$3x10^{-8}$ Torr	New Chemical Review (D226628, 2000); (25°C)
pK_a	6.8	http://www.aoac.org/pubs/JOURNAL/2001/ab8403.htm
log K_{ow}	5.0 (pH 7)	New Chemical Review (D226628, 2000)
Henry's law constant	3.8×10^{-10} atm m^3/mol	Product Chemistry; MRID 44883705
Hydrolysis half-life	$t_{½}$ = Stable	MRID 42743642; (pH 7)
Aqueous photolysis half-life	$t_{½}$ = 23 days	MRID 43850114 (natural sunlight - maximum value)
Soil photolysis half-life	$t_{½}$ = 5 days	MRID 43404302; (uncorrected for dark controls)
Aerobic soil metabolism half-life	$t_{½}$ = 193 days	MRID 43404303; (sandy loam)
Anaerobic soil metabolism	$t_{½}$ = 174 days	MRID 43850116
Anaerobic aquatic half-life	$t_{½}$ = 427 days	MRID 43850116
Adsorption coefficient K_{oc}	265,687 (average)	MRID 428515-26; K_{oc}= 279,000 - 730,000 - 25,382 - 28,365)
Bioconcentration factor (BCF)	69	MRID 434930-05; (whole fish)

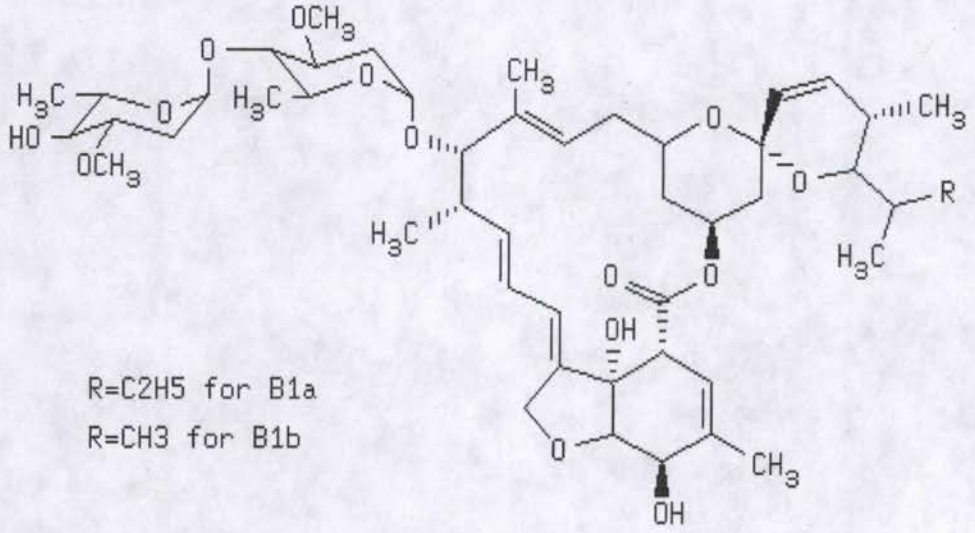

Figure 2.1. Structure of Emamectin Benzoate B1a and B1b

2.4. Approved Uses and Conclusions from Previous Assessments

Emamectin benzoate is currently registered for use on fruiting vegetables, brassica head and stem vegetables, leafy vegetables, and pome fruits. Current end use products include an emulsifiable concentrate (Proclaim 0.16 EC) and a water soluble concentrate (Proclaim 5 SG). It is applied by ground equipment or aerially as a foliar spray.

A number of risk assessments have been conducted for emamectin benzoate including a new chemical review in 2000 (D226628), new use reviews in 2002[1] and 2005[2], several Section 18 reviews[3]. However, none of the assessments included tree injection use. Primary risks identified in previous assessments included potential risks to aquatic and terrestrial invertebrates and mammals.

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[1]DP barcode 279840 and 279841 (cole crops, leafy vegetables, cotton, and tobacco).

[2]DP barcode 309154, Pome fruits

[3] DP barcodes include D223875, D223876, D239671, D239672; D255357, D279840, and D279841

2.5. Degradates of Concern

The Agency has identified four degradates of concern based on structural similarity to emamectin benzoate:

- (8,9-Z)-4"-epimethylamino-4"-deoxy avermectin B1 (8,9 ZMA isomer);
- 4"-epiamino-4"-deoxyavermectin B1 (AB);
- avermectin B1 monosaccharide (MAB); and
- 4"-epi-(N-formyl)-4"-deoxyavermectin B1 (FAB)

All of these degradation products form via photolysis of emamectin benzoate; the structures of these degradates are presented in Appendix A. For this assessment it is assumed that if these degradates form via tree injection, that they are as toxic to terrestrial animals as parent chemical. However, it is unknown if these degradates of concern form within injected trees.

2.6. Description of Proposed Use

The proposed new use of emamectin benzoate is a tree injection in ornamental trees. It is injected into active sapwood and is translocated in the tree's vascular system when injected.

It is applied by drilling a series of holes (5/8 to 2 inches deep past the bark) approximately 6 inches apart. Diameter of the holes is not specified on the label. The label states that optimum control occurs if application is made at the base of the tree; however, application may also be made around the stem within 12 inches of the soil, in the trunk flare, or into tree roots. It is unclear, however, how the labeled directions can be followed for injection into the tree roots. The amount of chemical to be added to each hole is not specified. If the holes drilled into the tree are filled until chemical spills out, then the potential for exposure to non-target organisms outside of the treated tree increases.

The amount of chemical injected depends on the size of the treated tree. The label indicates that up to approximately 50 mL per tree is applied to trees with a diameter of 4 to 6 inches and up to 1065 mL for trees with a diameter of 70 to 72 inches. The volumes presumably refer to mL of formulation and not mL of a.i. per tree; however, the label should specify mL product or mL a.i. Estimates of exposure assumed that the directions referred to mL of formulation product and were corrected for fraction of a.i. in the formulation. The amount of formulation that may be applied to various size trees as specified on the proposed label is summarized in Table 2.2.

Table 2.2. Summary of Application Rates for Various Tree Sizes			
Tree Diameter (DBH, Inches)	mL/tree applied[a]		Average No. of Injection Sites
	Low	High	
4 – 6	15	50	3
7 – 9	20	80	4
10 – 12	30	165	5
13 – 15	35	210	6
16 – 18	40	225	7
19 – 21	50	300	8
22 – 24	115	345	10
25 – 27	130	390	11
28 – 30	145	435	12
31 – 33	160	480	13
34 – 36	175	525	15
37 – 39	190	570	16
40 – 42	205	615	17
43 – 45	220	660	18
46 – 48	235	705	20
49 – 51	250	750	21
52 – 54	265	795	22
55 – 57	280	840	23
58 – 60	295	885	25
61 – 63	310	930	26
64 – 66	325	975	27
67 – 69	340	1020	28
70 – 72	355	1065	30

[a] These values presumably refer to mL of product and not mL of a.i. However, the label did not specify product or a.i. If the application rates refer to product, then this assessment would dramatically underestimate potential risks.

2.7. Conceptual Model

For a pesticide to pose an ecological risk, it must reach ecological receptors in biologically significant concentrations. An exposure pathway is the means by which a pesticide moves in the environment from a source to an ecological receptor. For an ecological pathway to be complete, it must have a source, a release mechanism, an environmental transport medium, a point of exposure for ecological receptors, and a feasible route of exposure.

The conceptual model for emamectin benzoate provides a written description and visual representation of the predicted relationships between emamectin benzoate, potential routes of exposure, and the predicted effects for the assessment endpoint. A conceptual model consists of two major components: risk hypothesis and a conceptual diagram (USEPA 1998).

Based on the use pattern and mode of action, labeled use of emamectin benzoate may pose potential risks to non-target organisms. Because of the potential risk from direct effects to non-target organisms, potential concerns exist for indirect effects on listed animals that eat potentially affected non-target organisms, listed plants that require these taxa as pollinators or seed dispersers, and listed animals that require mammal burrows for shelter or breeding habitat. This forms the basis of the risk hypothesis and conceptual diagram discussed below.

2.8. Risk Hypothesis

A risk hypothesis describes the predicted relationship among the stressor, exposure, and assessment endpoint response along with the rationale for their selection. For emamectin benzoate, the risk hypothesis for this ecological risk assessment is as follows:

> *Emamectin benzoate has the potential to reduce survival, reproduction, and/or growth in non-target terrestrial and aquatic animals including vertebrates and invertebrates when used in accordance with the current label. These non-target organisms include Federally listed threatened and endangered species as well as non-listed species.*

2.9. Conceptual Diagram

The potential routes of exposure to terrestrial organisms is expected to be primarily through consumption of various parts of the tree after emamectin benzoate has been translocated throughout the tree after injection. It is assumed that the pesticide may enter foliage, fruit, seeds, and pollen, which can in turn be used as food items by other organisms. In addition, secondary exposure may occur for animals that consume invertebrates that have been exposed to the chemical. There are no data on the rate of translocation or decay of emamectin benzoate in trees nor has the presence of transformation products in trees been evaluated. Degradates of toxicological concern have been identified; however, they have only been shown to form via photolysis, and it is unknown whether they may form within a treated tree. Available microbial metabolism studies suggest that emamectin benzoate does not degradate rapidly via metabolism. Therefore, the focus of this assessment is on the parent with the assumption that it does not degrade rapidly in treated trees. However, this assumption may be re-evaluated if a magnitude of residues study in trees is submitted.

Given the specificity of the tree injection use pattern, the predominant transport mechanism consists of translocation/uptake to foliage, fruit, seeds, and pollen in treated trees. The transport mechanism (*i.e.*, source) is depicted in the conceptual model below (**Figure 2.2**) along with the receptors of concern and the potential attribute changes in the receptors due to exposures of emamectin benzoate. The conceptual model also depicts

the potential for emamectin benzoate residues in leaves, fruits, and seeds to enter adjacent water bodies.

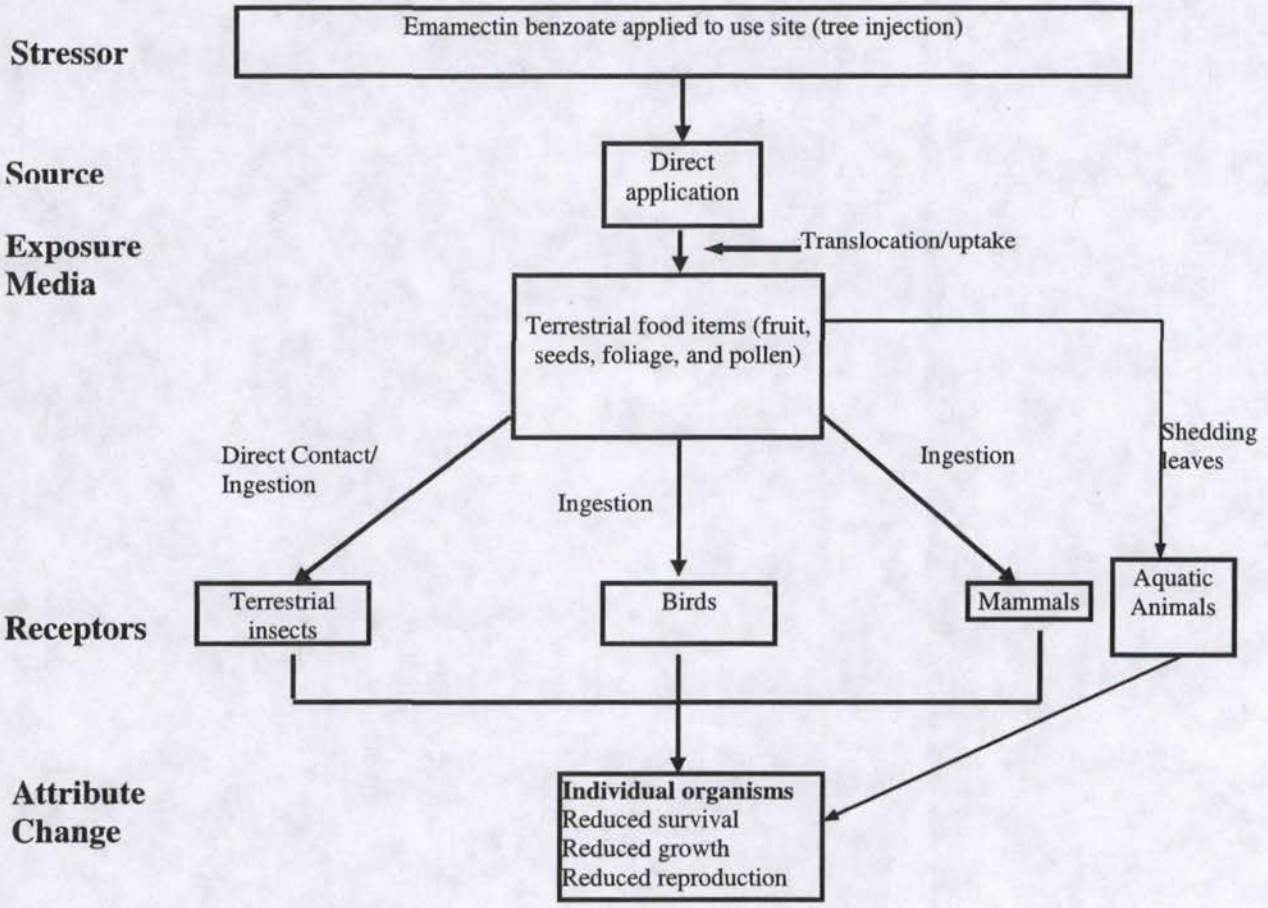


Figure 2.2. Conceptual Model for Emamectin Benzoate Application via Tree Injection

2.10. Assessment Endpoints

Assessment endpoints represent the actual environmental value that is to be protected, defined by an ecological entity (species, community, or other entity) and its attribute or characteristics (USEPA 1998). For the proposed use of emamectin benzoate, the ecological entities may include birds, mammals, and terrestrial insects that feed on translocated residues of emamectin benzoate in fruit, seeds, foliage, and pollen. The attributes for each of these entities may include growth, reproduction, and survival.

2.11. Environmental Fate and Transport

The environmental fate database has been discussed in depth in previous assessments (New Chemical Review, 2000; D226628) and is considered essentially complete. A brief summary of emamectin benzoate's environmental fate profile and a summary of

transformation/dissipation half-lives and BCF values are provided below. Previous reviews may be referenced for additional information.

Terrestrial Environments. Mobility studies conducted with emamectin benzoate indicate that the parent compound and its degradates would be expected to be relatively immobile in the environment due to a high degree of sorption to soil particles (K_d 219 to 2037). Therefore, most of the emamectin benzoate that enters the terrestrial environment is expected to remain at the site of application until it degrades or is transported via soil erosion. For this reason, high levels of parent and/or transformation products are not expected to enter surface water through runoff or to leach into ground water. The low emamectin benzoate vapor pressure suggests that volatilization from soil is expected to be minimal. Emamectin benzoate is resistant to microbial degradation (half-life 174 days) and hydrolysis (half-life 193 days), and is expected to be persistent when it is attenuated from light. The primary environmental dissipation pathway of emamectin benzoate is expected to be through photolysis on soil (half-life 5 days); however, degradation within injected trees has not been evaluated.

Aqueous Environments. Emamectin benzoate is expected to enter the water primarily through soil erosion. For the proposed use pattern, the pesticide could also enter the water directly via falling leaves or other tree parts. Once in an aquatic system, emamectin benzoate is likely to remain bound to sediment or suspended particles. It does not hydrolyze in water at pH 5 to 8, but slowly hydrolyzes at pH 9 (half-life 20 weeks). Its low Henry's Law constant suggests that volatilization from water is likely to be negligible. Although emamectin benzoate degrades rapidly through aqueous photolysis, other than in oligotrophic systems (clear, shallow water bodies with low in organic matter content), aqueous photolysis is not likely to significantly contribute to the degradation of emamectin benzoate. It is also not expected to bioconcentrate to any appreciable extent (whole fish BCF = 69).

2.12. Analysis Plan

2.12.1 Measures of Exposure

Evaluating exposure for this use pattern requires information on concentrations of the pesticide in animal food items after the chemical is translocated throughout the tree from the application site. This information is not available for emamectin benzoate. Therefore, exposure estimates used in this assessment are screening level estimates that are used to determine the value of additional data that may refine exposure estimates. This screen is based on the following assumptions:

(1) Total mass of chemical applied

a. **Terrestrial Assessment:** The total mass of chemical applied to the tree was compared to toxicity values of terrestrial animals; **EEC = total mass of chemical applied**

b. **Aquatic Assessment-1**: The total mass of chemical applied to the tree was assumed to enter a 20,000,000 L water body directly; **EEC = total mass of chemical / concentration of water**

c. **Aquatic Assessment-2**: The total mass of chemical applied to the tree was assumed to be available for runoff to a nearby water body; **EECs were estimated using GENEEC2 assuming that 100% of the chemical reached the soil.**

(2) Whole tree concentration

a. Whole tree concentration was estimated by assuming that the chemical was evenly distributed within the tree. Estimates of tree mass were based on information published by the University of Arkansas Cooperative Extension Service; **EEC = total mass of chemical applied / mass of tree**.

(3) Concentration of chemical in leaves

a. Leaf concentration was estimated by assuming that 100% of the chemical was translocated to the leaves. Leaf mass was estimated using allometric equations developed for blue oak trees presented by the USDA Forest Service (2002). **EEC = total mass of chemical applied / leaf mass on tree**.

2.12.2 Measures of Effects

Measures of ecological effects are obtained from a suite of registrant-submitted guideline studies conducted with a limited number of surrogate species. The test species are not intended to be representative of the most sensitive species but rather were selected based on their ability to thrive under laboratory conditions. Consistent with EPA test guidelines, a suite of ecological effects data on technical grade emamectin benzoate that complies with good laboratory testing requirements has been submitted. These data are summarized in Section 4.

2.12.3 Measures of Risk

The exposure and toxicity data are integrated in order to evaluate the potential risks of adverse ecological effects on non-target species. The risk quotient (RQ) method was used to compare exposure and toxicity values. EECs are divided by acute and chronic toxicity values. The resulting RQs are then compared to the Agency's levels of concern (LOCs). Risk presumptions, along with the corresponding RQs and LOCs for terrestrial animals are summarized in Table 2.3. However, the exposure estimates used in this assessment are screening level estimates that inform the risk assessor of potential value of data to allow for refinements, and the RQs associated with LOCs in Table 2.2 my be interpreted differently than the RQs presented in this assessment.

Table 2.3. Risk Presumptions and LOCs

Risk Presumption	RQ	LOC
Birds[1]		
Acute Risk	EEC/LC_{50} or LD_{50}/sqft or LD_{50}/day	0.5

Table 2.3. Risk Presumptions and LOCs		
Risk Presumption	**RQ**	**LOC**
Acute Restricted Use	EEC/LC_{50} or LD_{50}/sqft or LD_{50}/day (or LD_{50} < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC_{50} or LD_{50}/sqft or LD_{50}/day	0.1
Chronic Risk	EEC/NOEC	1
Mammals[1]		
Acute Risk	EEC/LC_{50} or LD_{50}/sqft or LD_{50}/day	0.5
Acute Restricted Use	EEC/LC_{50} or LD_{50}/sqft or LD_{50}/day (or LD_{50} < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC_{50} or LD_{50}/sqft or LD_{50}/day	0.1
Chronic Risk	EEC/NOEC	1

[1] LD_{50}/sqft = (mg/sq ft) / (LD_{50} * wt. of animal)
LD_{50}/day = (mg of toxicant consumed/day) / (LD_{50} * wt. of animal)

3. Exposure Analysis

Because the proposed use pattern is limited to tree injection, the major route of exposure to terrestrial organisms is expected to occur through uptake and translocation of the chemical to foliage, fruit, pollen, and seeds which can be used as food items. However, organisms could also be exposed to emamectin benzoate if it spills from the injection site or as a result of the chemical entering the terrestrial or aquatic environment via fallen leaves or other tree parts. Biodegradation data suggest that emamectin benzoate does not biodegrade fast.

In order to quantitatively assess exposure, data pertaining to the amount and rate of translocation and decay of emamectin benzoate in ornamental trees following application are needed. This type of data would facilitate estimation of potential residues in foliage/fruit/pollen which can be used as food items for terrestrial organisms. Currently, there are no data on the rate of translocation or decay of emamectin benzoate in trees after injection. Therefore, quantitative estimates of exposure are difficult. As a conservative screening approach, three exposure approaches were used to estimate exposures that were based on (1) total mass of emamectin benzoate applied to various sizes of trees (terrestrial and aquatic EECs), (2) estimated concentration in leaves assuming 100% of the chemical translocates to the leaves, and (3) estimated whole tree concentrations as further described in the following sections. In order to refine these exposure estimates, data that evaluate uptake, translocation, and degradation of emamectin benzoate *in situ* are needed.

3.1. Estimates of Exposure Based on Total Mass of Emamectin Benzoate Applied to Various Tree Sizes

3.1.1. Terrestrial EECs

A range of the total mass of emamectin benzoate that may be applied to trees is summarized in Table 3.1. These values were compared with terrestrial animal toxicity values to determine if there is a potential for LOC exceedances.

Table 3.1. Exposure Screen for Emamectin Benzoate for Tree Injection

Tree Size (diameter, in)	Amount of formulation injected (from proposed label)	
	mL formulation (from label)	mg a.i. (calculated assuming density of 1 g/mL)[a]
Small, 4 – 6 in.	15 to 50	600 to 2000 mg a.i.
Large, 70 – 72 in.	355 to 1065	14,000 to 42,600 mg a.i.

[a] Product label specified volume of product applied to each tree. Mass was calculated using the following equations:

mL product/tree (given on label) x 0.04 (4% a.i. in formulation) = mL a.i./tree
mL a.i./tree x 1000 mg/mL (density of water; density of product not available) = mg a.i./tree

3.1.2. Aquatic EECs

There is also potential for aquatic systems to be exposed to emamectin benzoate either directly from contaminated tree parts (e.g., leaves, sticks, flowers, pollen) entering the water or from tree parts falling onto land and subsequent runoff into aquatic systems. As a screen, the total amount of chemical applied to a tree was added to a 20,000,000 liter pond. The resulting water concentration would result in a conservative screen, but could be used to preclude risks to taxonomic groups if no LOCs are exceeded. The resulting pesticide concentrations range from 0.03 ug/L to 2 ug/L (600 ug/L to 42,600 ug / 20,000,000 L = 0.03 ug/L to 2.1 ug/L) depending on the amount of pesticide applied to the tree.

In addition, aquatic exposures could occur from the chemical entering soil environments and subsequently entering aquatic environments. This could occur if the chemical is translocated primarily to the leaves, and the leaves fall to the soil and decompose. As an initial screen, it was assumed that the total mass of the chemical applied to a tree via injection was applied directly to soil. Assuming 1 tree per acre is treated, the applied mass was used as an application rate (lbs a.i./Acre), and GENEEC2 was used to estimate potential aquatic concentrations. The application rate resulting from 600 mg (small tree) 42,600 mg (large tree) would be 0.001 lbs a.i./Acre to 0.094 lbs a.i./Acre (600 mg/tree to 42,600 mg/tree / 453592 mg/lb x 1 tree/acre = 0.001 lbs a.i./Acre to 0.094 lbs/Acre). The upper end of the range could represent application to one large tree or numerous smaller trees per acre.

Using these values as application rates and inputting the chemical properties for emamectin benzoate listed in Table 2.1 (page 7) results in peak EECs that range from

0.003 ug/L to 0.2 ug/L. Outputs from the modeling exercise are in Appendix B. These EECs are intended as screening level values that can be used to preclude potential risks to taxonomic groups if toxicity data indicate that effects are not likely to occur at these levels. If LOCs are exceeded based on these EECs, then additional refinements are needed to better characterize potential risks.

3.2. Estimates of Exposure Based on Estimated Whole Tree Concentrations and Leaf Concentrations

The tree injection formula of emamectin benzoate is designed to be distributed throughout the tree, and the fate of the chemical within a tree after injection is uncertain. Therefore, potential exposures to terrestrial organisms that feed on treated trees were estimated using estimated whole tree concentrations and leaf concentrations. These estimates were used to determine the value of a magnitude of residues study that measures potential exposures to organisms that may feed on treated trees.

Whole tree concentration estimates assume that the chemical is evenly distributed throughout the tree. Submission of a magnitude of residues study would reduce uncertainty in these estimates. Pesticide mass applied to trees was obtained from the proposed label. Tree weight estimates were obtained from the Cooperative Extension Service of the University of Arkansas, and they represent estimates for standing hardwood trees. The estimate was based on the merchantable portion of the tree (portion from a 1 foot stump to the top of a tree that is <4 inches in diameter). The estimate does not include tops, foliage, or limbs and, therefore, provides a conservative measure of whole-tree concentration. However, the estimates were within the range reported for above ground biomass for similar size trees reported by the U.S. Forest Service (1982). Therefore, the estimate was not further refined for this assessment.

The largest tree included in the publication was a 36 inch DBH tree. Therefore, estimates were only made for this assessment for trees that range from 12 to 36 DBH (inches). Whole-tree concentrations were compared with toxicity values to characterize potential risks to terrestrial organisms.

Table 3.2. Range of Whole Tree Concentration Estimates of Emamectin Benzoate

DBH	Tree Wt (kg)	Mass of pesticide injected in tree (mg)	Whole-tree pesticide concentration (mg/kg)
12 in	680	6600	9.8
36 in	7400	21000	2.8

Emamectin benzoate concentration was also estimated in leaves of treated trees. Estimated leaf concentrations resulting from tree injection assume that 100% of the chemical was translocated to the leaves and that the chemical was evenly distributed across the leaf mass. Submission of a magnitude of residues study would reduce uncertainty in these assumptions.

Pesticide mass applied to trees was obtained from the proposed label (Table 2.2). Estimated leaf mass was based on an allometric equation for oak trees published by the USDA Forest Service that relate tree size to estimated leaf mass (USDA Forest Service Gen. Tech. Rep. PSW-GTR-184. 2002):

$$\text{Leaf mass (g)} = 1.78x^2 - 12.4x - 108.5$$
$$x = \text{tree circumference at breast height (cm)}$$

Resulting estimates of leaf concentrations are summarized in Table 3.3. The resulting leaf concentration estimates were compared to toxicity values from terrestrial organisms to characterize potential risks.

Table 3.3. Range of Estimated Concentrations of Emamectin Benzoate in Leaves

DBH (in.)	Leaf mass (kg)	Pesticide mass (mg)	Pesticide concentration (mg/kg)
4	1.1	600	510
36	130	21,000	160
72	530	42600	80

4. Ecotoxicity Data

Toxicity reference values used in this assessment are presented in Table 4.1. Additional details are included in previous assessments. The effects database is relatively complete. Data gaps noted in the previous assessment (DP 309154) included the following (details are provided in DP 309154):

- Acute and chronic studies in sediment dwelling organisms (chemical is expected to partition to and persist in sediment);
- lack of an acceptable life-cycle study in mysid shrimp;
- more sensitive analytical detection methodology;
- terrestrial plant toxicity data;
- and degradate toxicity data.

In addition, submission of an acute oral study in bees would be valuable to this assessment.

Table 4.1. Summary of Toxicity Values Used in This Assessment					
Species	**Toxicity Value**	**Probit Slope (95% C.I.)**	**Toxicity Category**	**MRID No.**	**Comment**
Acute Studies					
Mallard duck *(Anas platyrhynchos)*	LD_{50}Adj: 23 mg/kg-bw	3.5 (1.9-5.2)	highly toxic	42743601	**Acceptable** study. Consumption of 0.46 mg would result in LD50 dose for a 20-gram bird (23 mg/kg-bw * 0.02 kg-bw = 0.46 mg)
Laboratory mouse *(Mus musculus)*	LD_{50}Adj: 24 mg/kg-bw	Not calculated	highly toxic	42743612	**Acceptable** study. Consumption of 0.36 mg would result in LD50 dose for a 15-gram mammal (24 mg/kg-bw * 0.015 kg-bw = 0.36 mg)
Honey bee *(Apis mellifera)*	LD_{50} 3.5 ng/bee	--	Highly Toxic	42851530	Acceptable study. Emamectin benzoate residues on foliage sprayed at 0.015 lbs ai/acre remain lethal to honeybees for 8 to 24 hours post-application (Palmer, 1994; MRID 43393006).
Rainbow trout *(Oncorhynchus mykiss)*	LC_{50}: 174 ug/L	7.0 (3.6-10)	Highly toxic	42851529	**Acceptable** study.
Waterflea *(Daphnia magna)* Flow-through	EC_{50}: 1.0 ug/L	4.7 (3.2-6.2)	Very highly toxic	42743603	**Acceptable** study.
Eastern oyster *(Crassostrea virginica)* (shell deposition or embryo-larvae) Flow-through	EC_{50}: 490 ug/L	4.9 (C.I. not reported)	Highly toxic	43393002	**Acceptable** study.
Mysid *(Americamysis bahia)* Flow-through	LC_{50}: 0.04 ug/L	8.1 (4.9 - 11.2)	Very highly toxic	43393001	**Acceptable** study.
Chronic Studies					

Mallard duck *(Anas platyrhynchos)*	NOEC: 40 mg/kg-diet	Not applicable	Not applicable	44007910	No adverse effects observed at any endpoint
870.3800 Reproductive Toxicity-Rat MK-0244	NOAEC: 0.6 mg/kg-bw/day	Not applicable	Not applicable	42851511	**LOAEL=1.8 mg/kg/day** based on decreased fecundity and fertility indices and clinical signs (tremors and hind limb extension) in offspring of both generations.
Fathead Minnow *(Pimephales promelas)*	Early Life Stage NOAEC: 6.5 ug/L	Not applicable	Not applicable	43850107	**Acceptable** study.
Waterflea *(Daphnia magna)* Flow-through	NOAEC: 0.088 ug/L	Not applicable	Not applicable	43393004	**Acceptable** study.
Mysid *(Americamysis bahia)* Flow-through	NOAEC: 0.018 ug/L	Not applicable	Not applicable	44305601	**Supplemental** study.
	NOAEC: 0.0087 ug/L	Not applicable	Not applicable	45833001	**Supplemental** study.
Aquatic Plant Studies					
Vascular Plant-Duckweed *Lemna gibba* Static	EC_{50} > 94 ug/L NOEC: 94 ug/L	Not applicable	Not applicable	43850109	**Acceptable** study.
Freshwater algae *Selenastrum capricornutum* Static	EC_{50} > 3.9 ug/L NOEC < 3.9 ug/L	Not applicable	Not applicable	43850108	**Acceptable** study.

4.1. Incident Database Review

No incidents are included in the EIIS database.

5. Risk Characterization

Risk characterization is the integration of exposure and ecological effects characterization to determine the potential ecological risk from the use of emamectin benzoate as a tree injection fungicide and the likelihood of direct and indirect effects to non-target organisms in terrestrial habitats. The exposure and toxicity effects data are integrated in order to evaluate the risks of adverse ecological effects on non-target species. For the assessment of emamectin benzoate risks, the risk quotient (RQ) method is used to compare exposure and measured toxicity values. EECs are divided by acute and chronic toxicity values. The resulting RQs are then compared to the Agency's Levels of Concern

(LOCs) (USEPA 2004). These criteria are used to indicate when emamectin benzoate's uses, as directed on the label, have the potential to cause adverse direct or indirect effects to non-target organisms. In addition, incident data from the EIIS will be considered as part of the risk characterization.

5.1. Risk Characterization

Potential risks to terrestrial organisms are described below. The lack of quantifiable exposure levels precludes derivation of refined RQs. Submission of a study that measures the fate, uptake and translocation (magnitude of residue study) of emamectin benzoate in ornamental trees to estimate exposure to honey bees, pollinators, and other terrestrial animals is of high value to this assessment. This type of study requires a formal protocol. Data on the magnitude of residues in leaves, pollen, and nectar are needed to derive reliable estimates of exposures. Because such a study is currently not available, the risk estimates included in this assessment are screening level estimates of risk.

5.1.1. Potential Risks to Terrestrial Animals

The adjusted LD50 for birds and mammals is approximately 20 mg/kg-bw, which corresponds to consumption of approximately 0.4 to 0.5 mg for a 15- to 20-gram animal. Therefore, consumption of 0.04 to 0.05 mg or more would result in exceedance of the endangered species LOC of 0.1.

Concentrations of emamectin benzoate of approximately 2, 10, and 20 mg/kg-food or higher in food items would result in EECs that exceed the endangered species LOC, acute LOC, and the LD50, respectively, for a 15 to 20-gram animal. As shown in Table 5.1, screening level EECs exceeded levels that may result in potential effects to terrestrial organisms.

Table 5.1. Risk Summary for Terrestrial Animals

Screening EEC		Toxicity Value			
Assumption	**EEC**	**Birds**	**Mammals**	**Inverts.**	**Risk Summary**
Total Mass	600 mg – 42,000 mg	0.46 mg	0.36 mg	3.5 ng/bee	Sufficient mass is available to potentially affect birds, mammals, and invertebrates
Whole-tree conc.	Birds: 3 – 11 mg/kg-bw[a] Mammals: 3 – 10 mg/kg-bw[a]	23 mg/kg-bw	24 mg/kg-bw	3.5 ng/bee	Estimated concentrations of emamectin benzoate are sufficient to result in potential risks to terrestrial animals.
Leaf Conc.	Birds: 91 – 570 mg/kg-bw[a] Mammal: 76 – 780 mg/kg-bw[a]	23 mg/kg-bw	24 mg/kg-bw	3.5 ng/bee	Estimated concentrations of emamectin benzoate are sufficient to result in potential risks to

					terrestrial animals.

[a] Pesticide concentration on leaves was converted to dose by assuming that birds and mammals consume 114% and 95% of their body weight daily. Estimated pesticide concentration was 80 – 500 mg/kg-leaf and 3 to 10 mg/kg-whole tree.

The total mass of emamectin benzoate applied to treated trees ranges from 600 mg to 42,000 mg. Therefore, there is sufficient mass applied to trees to potentially affect birds and mammals. The fraction of the mass of emamectin benzoate applied to a tree consumed by a 20-gram bird would need to be less than 0.0001 (0.01%) of the total mass applied for a small tree and <0.000001% (>0.0001%) of the total mass applied for a large tree to result in no LOC exceedances for birds.

Consideration of dilution within the tree did not reduce potential risks to levels that are below concern levels. Estimated leaf concentrations were sufficient to result in risk concerns for organisms that may eat leaves of treated trees. This evaluation assumed that 100% of the injected chemical was translocated to the leaves. However, even translocation of a relatively small fraction of emamectin benzoate to the leaves could result in potential effects to terrestrial organisms. Estimates of whole-tree pesticide concentrations assuming that the chemical is evenly distributed throughout the above ground biomass were also above levels that may be of concern to non-target terrestrial animals. Therefore, the available data suggest that potential risks to non-target terrestrial organisms are of concern. Submission of a magnitude of residues study that quantifies potential exposure levels after tree injection would be of high value to this risk assessment. Risks may be further quantified and refined if a magnitude of residues study in treated trees is submitted that evaluates concentrations of emamectin benzoate in edible parts of treated trees, including leaves, nectar, fruit, seeds, and pollen.

The above analysis only considered potential acute effects. However, there is also potential for repeated or prolonged exposures to terrestrial animals because emamectin benzoate is not expected to rapidly dissipate from trees after it is injected and translocated. Therefore, there is also potential risk to reproduction endpoints from the proposed tree injection use.

5.1.2. Potential Risks to Aquatic Organisms

There is also potential for aquatic systems to be exposed to emamectin benzoate either directly from contaminated tree parts (e.g., leaves, sticks, flowers, pollen) entering the water or from tree parts falling onto land and subsequent runoff into aquatic systems. As a screen, the total amount of chemical applied to a tree was added to a 20,000,000 liter pond. In addition, aquatic exposures could occur from the chemical entering soil environments and subsequently entering aquatic environments as described in Section 3. The resulting water concentration would result in a conservative screen, but could be used to preclude risks to taxonomic groups if no LOCs are exceeded. EECs and toxicity values are summarized in Table 5.2.

Table 5.2. Risk Summary for Aquatic Animals					
Screening EEC		**Toxicity Value (ug/L)**			**Risk Summary**
Assumption	**EEC**	**Fish**	**Invert**	**SW Invert**	
Direct Deposition	0.03 ug/L to 2 ug/L	LC50: 174 NOAEC: 6.5	EC50: 1 NOAEC: 0.09	LC50: 0.04 NOAEC: 0.009	Fish are not likely at risk of effects from the tree injection use of emamectin benzoate under the assumptions of this risk assessment. However, potential risks to aquatic invertebrates could not be precluded.
Runoff from Soil	0.003 ug/L to 0.2 ug/L				

This analysis indicates that potential risks to aquatic invertebrates cannot be precluded. However, potential risks to fish are not likely to exceed LOCs. Submission of a magnitude of residues study previously described would be of high value to this assessment and may allow for further refinement of the EECs included in table 5.2.

5.1.3. Summary

This analysis suggests that translocation of a small fraction of emamectin benzoate from the site of injection to edible portions of a tree may result in effects to birds, mammals, and non-target invertebrates. Potential risks to aquatic invertebrates could not be precluded. Additional data, including a magnitude of residues study in injected trees and an acute oral study in bees are needed to allow for refinements of potential risks.

5.2. Uncertainties and Data Gaps

There is currently no standard methodology for evaluating potential ecological risks from application of pesticides via tree injection. This assessment was based on conservative estimates of exposure, and a primary uncertainty in this assessment is that the screening level exposure estimates cannot be refined based on the currently available data. Screening level exposure values were used in this assessment that identified potential risks to non-target aquatic and terrestrial animals. However, these screening-level values were likely conservative, and submission of a magnitude of residues study that evaluates pesticide concentrations in various parts of the tree that may serve as food for birds, mammals, and invertebrates is necessary to allow for refinements of potential risks. This type of study requires submission of a formal protocol by the registrant.

The fate of the pesticide within the tree is also largely unknown. It was assumed that emamectin benzoate may leach from leaves or other parts of a tree after they have fallen to the ground. However, the fate of the chemical within the tree remains unknown. Also, degradates of toxicological concern were observed to form via photolysis. It is not known if degradates of concern form within a treated tree, and if they do form, to what extent non-target organisms may be exposed.

Estimates of exposure included estimations of pesticide concentrations in leaves and in the whole tree. Estimated pesticide concentrations in leaves were determined by assuming that 100% of the chemical is translocated to leaves. Leaf mass was estimated using the following allometric equation developed for blue oak trees presented by the USDA Forest Service (2002):

$$\text{Leaf mass (g)} = 1.78x^2 - 12.4x - 108.5$$
$$x = \text{tree circumference at breast height (cm)}$$

The regression was developed based on a study of 14 blue oak trees harvested in the Sierra Nevada foothills with an r^2 value of 0.98. The extent to which the equation estimates leaf mass for other types of trees or for blue oak trees in other locations has not been evaluated for this assessment.

Estimates of pesticide concentration in the whole tree assumed that the chemical was evenly distributed within the tree and required an estimate of tree mass. Estimates of tree mass were based on information published by the University of Arkansas Cooperative Extension Service and included only the merchantable portion of the tree (portion from a 1 foot stump to the top of a tree that is <4 inches in diameter). The estimate does not include tops, foliage, or limbs and is, therefore, provides a conservative measure of whole-tree concentration. However, the estimates were within the range reported for above ground biomass (dry weight) for similar size trees reported by the U.S. Forest Service (1982) when corrected for water content assuming a range of water content of 10% to 50% by weight. Therefore, the estimate was not further refined for this assessment. However, use of a whole tree concentration may not be conservative because the estimate assumes that the pesticide is evenly distributed throughout the tree, which could lead to an underestimation of exposure and risk if the chemical concentrates in an edible portion of the tree.

Aquatic exposure estimates assumed either that 100% of the chemical entered the soil and was available for runoff or that 100% of the chemical entered a water body directly. These are conservative estimates of exposure to aquatic organisms. Submission of a magnitude or residues study previously discussed may allow for refinement of potential aquatic exposures. Also, leaves and some other tree parts that enter the water could ultimately end up in the sediment. Exposure estimates for sediment organisms were not included in this assessment.

Also, given the high toxicity of emamectin benzoate to terrestrial invertebrates and that the dietary exposure route is likely to be an important exposure route due to the administration route of tree injection, an acute oral toxicity study in bees would also be of high value to this assessment. Submission of a magnitude of residues study previously described may reduce these uncertainties.

6. References

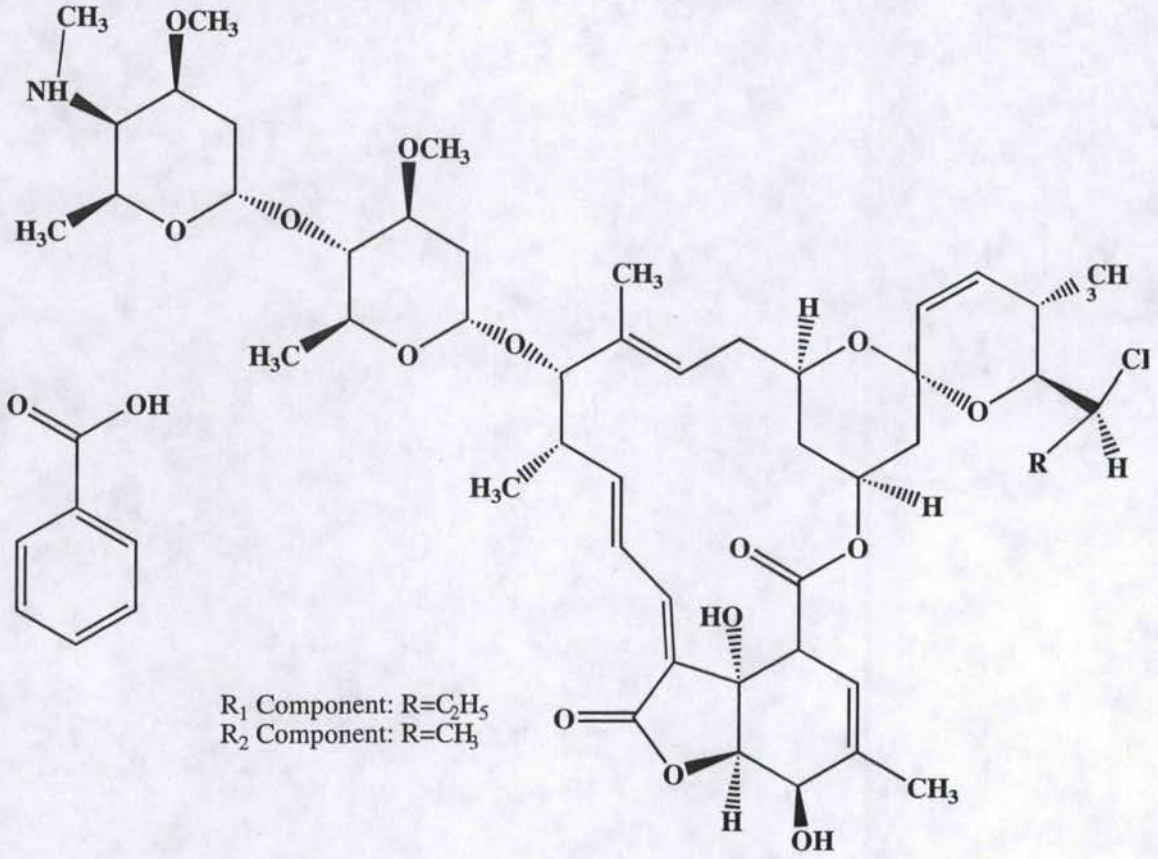
USDA Forest Service (John F. Karlik and Alistair H. McKay). 2002. Leaf area index, leaf mass density, and allometri relationships derived from harvest of blue oaks in California oak Savanna. USDA Forest Service Gen. Tech. Rep. PSW-GTR-184.2002.

USDA Forest Service (Louise M. Tritton and James W. Hornbeck). 1982. Biomass Equations for Major Tree Species of the Northeast. General Technical Report NE-69.

University of Arkansas Division of Agriculture (David W. Patterson). Undated. Landowner's guide to determining weight of standing hardwood trees. University of Arkansas Division of Agriculture, Cooperative Extension Service. FSA 5021.

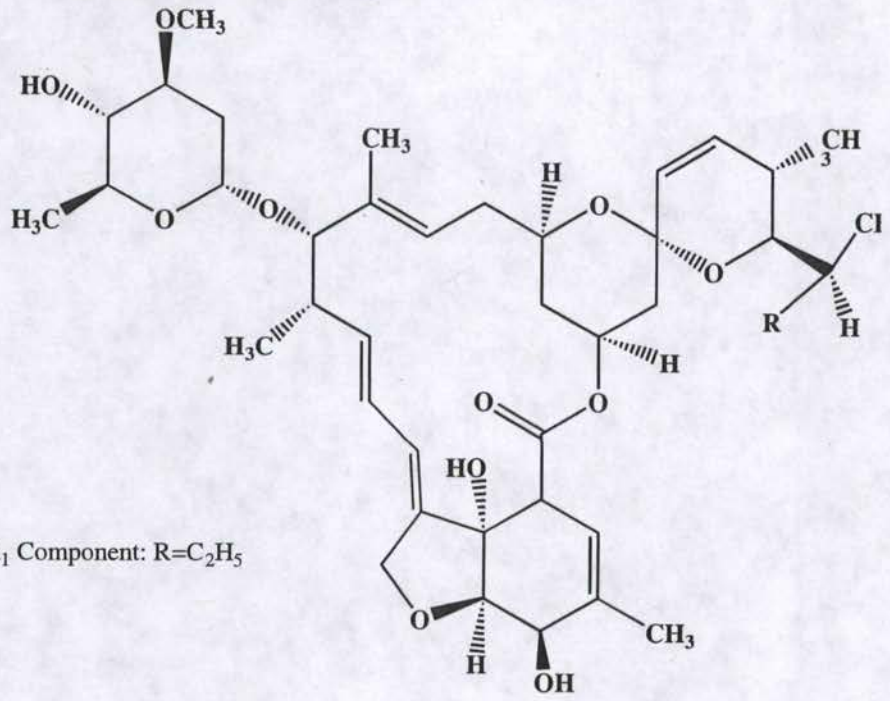
Appendix A. Structure of Degradates of Concern

Degradate 2: 8,9-Z MA ((8,9-Z)-4"-epimethylamino-4"-deoxy anermectin B1)

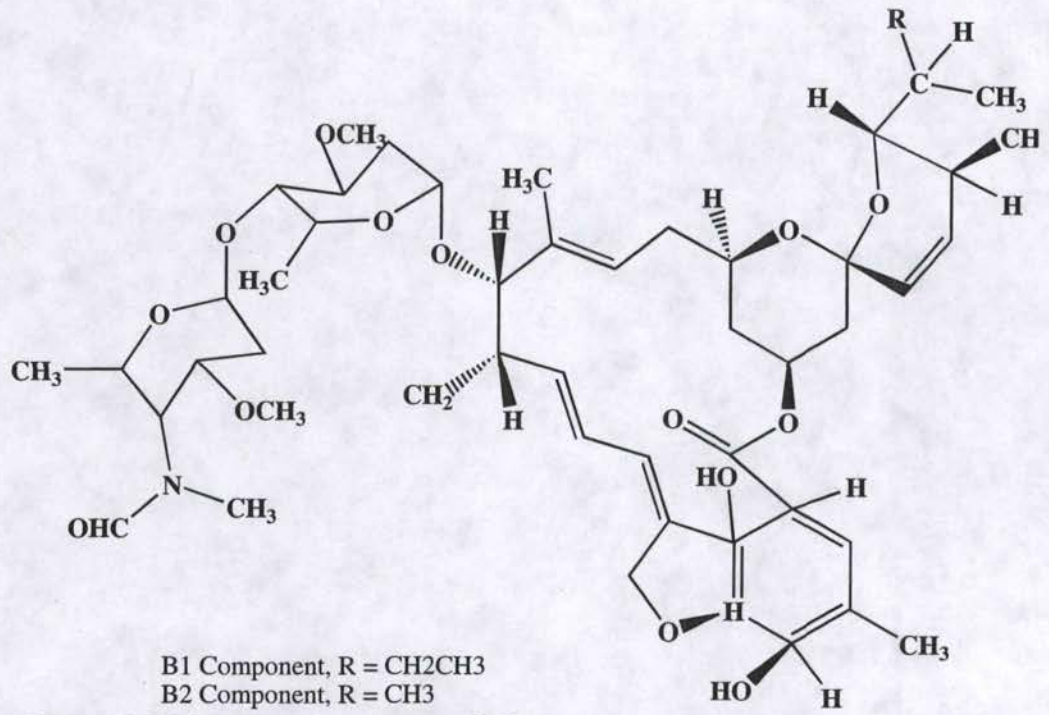


R_1 Component: R=C_2H_5
R_2 Component: R=CH_3

MAB1a (avermectin B1 monosaccharide)



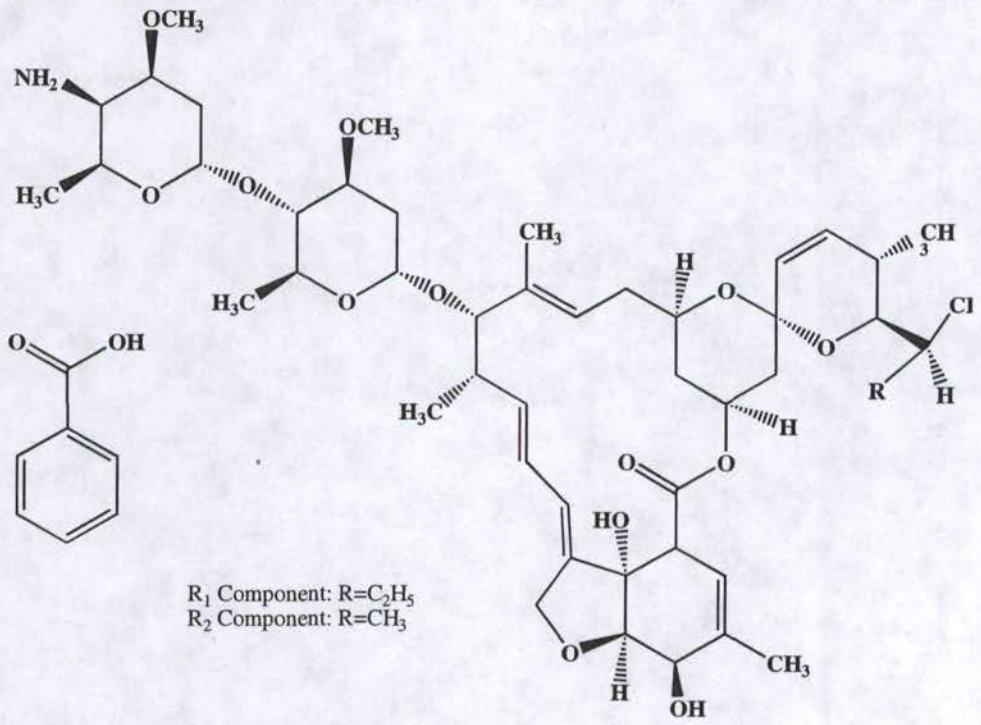
R_1 Component: R=C_2H_5



B1 Component, R = CH2CH3
B2 Component, R = CH3

FAB (4"-epi-(N-formyl)-4"-deoxyavermectin B1)

AB1a (4"-epiamino-4"-deoxyavermectin B1)



R_1 Component: R=C_2H_5
R_2 Component: R=CH_3

Appendix B. GENEEC2 Output

RATE (#/AC) ONE(MULT)	No.APPS & INTERVAL	SOIL Koc	SOLUBIL (PPM)	APPL TYPE (%DRIFT)	NO-SPRAY (FT)	INCORP (IN)
.093(.093)	1 1	265687.0	93.0	GRANUL(.0)	.0	.0

FIELD AND STANDARD POND HALFLIFE VALUES (DAYS)

METABOLIC (FIELD)	DAYS UNTIL RAIN/RUNOFF	HYDROLYSIS (POND)	PHOTOLYSIS (POND-EFF)	METABOLIC (POND)	COMBINED (POND)
193.00	2	N/A	23.00- 2852.00	386.00	339.99

GENERIC EECs (IN NANOGRAMS/LITER (PPTr)) Version 2.0 Aug 1, 2001

PEAK GEEC	MAX 4 DAY AVG GEEC	MAX 21 DAY AVG GEEC	MAX 60 DAY AVG GEEC	MAX 90 DAY AVG GEEC
225.42	141.80	35.39	4	8.41

RUN No. 12 FOR Emamectin Benzoa ON Trees * INPUT VALUES *

RATE (#/AC) ONE(MULT)	No.APPS & INTERVAL	SOIL Koc	SOLUBIL (PPM)	APPL TYPE (%DRIFT)	NO-SPRAY (FT)	INCORP (IN)
.001(.001)	1 1	265687.0	93.0	GRANUL(.0)	.0	.0

FIELD AND STANDARD POND HALFLIFE VALUES (DAYS)

METABOLIC (FIELD)	DAYS UNTIL RAIN/RUNOFF	HYDROLYSIS (POND)	PHOTOLYSIS (POND-EFF)	METABOLIC (POND)	COMBINED (POND)
193.00	2	N/A	23.00- 2852.00	386.00	339.99

GENERIC EECs (IN NANOGRAMS/LITER (PPTr)) Version 2.0 Aug 1, 2001

PEAK GEEC	MAX 4 DAY AVG GEEC	MAX 21 DAY AVG GEEC	MAX 60 DAY AVG GEEC	MAX 90 DAY AVG GEEC
3.15	1.98	.49	.18	.12

DP Barcode: 381025 MRID No.: 48257501

DATA EVALUATION RECORD
HONEY BEE - ACUTE CONTACT & ORAL LC_{50} TEST
'141-1

1. **CHEMICAL:** Emamectin Benzoate PC Code No.: 122806

2. **TEST MATERIAL:** MK 244 05 SG (AI: Emamectin Benzoate)
Purity: 4.75% (analyzed)

3. **CITATION**

Authors:	Barth, M.
Title:	Acute toxicity of MK 244 05 SG (A-10324 A) to the honeybee *Apis mellifera* L. under laboratory conditions.
Study Completion Date:	July 26, 2001
Laboratory:	BioChem agrar, Gerichshain, Germany
Sponsor:	Syngenta Crop Protection AG, Basel, Switzerland
Laboratory Report ID:	01 10 48 027
MRID No.:	48257501
DP Barcode:	381025

4. **REVIEWED BY:** Moncie Wright, Staff Scientist, Cambridge Environmental Inc.

Signature: Moncie V Wright **Date:** 10/27/10

APPROVED BY: Teri S. Myers, Senior Scientist, Cambridge Environmental Inc.

Signature: Teri S Myers **Date:** 11/29/10

5. **APPROVED BY:** Pamela M. Hurley, Toxicologist, OPP/EFED/ERB3

Signature: Pamela M Hurley **Date:** 12/01/2010

6. **DISCLAIMER:** This document provides guidance for EPA and PMRA reviewers on how to complete a data evaluation record after reviewing a scientific study concerning the acute toxicity of a pesticide to honey bees via oral and contact exposure routes. It is not intended to prescribe conditions to any external party for conducting this study nor to establish absolute criteria regarding the assessment of whether the study is scientifically sound and whether the study satisfies any applicable data requirements. Reviewers are expected to review and to determine for each study, on a case-by-case basis, whether it is scientifically sound and provides sufficient information to satisfy applicable data requirements. Studies that fail to meet any of the conditions may be accepted, if appropriate; similarly, studies that meet all of the conditions may

be rejected, if appropriate. In sum, the reviewer is to take into account the totality of factors related to the test methodology and results in determining the acceptability of the study.

7. STUDY PARAMETERS:

Scientific Name of Test Organism:	*Apis mellifera carnica* L.
Age of Test Organism at Test Initiation:	Worker bees
Type of Concentrations:	Nominal (contact test) and Actual (oral test)
Definitive Test Duration:	96 hours

8. CONCLUSIONS:

The honey bee, *Apis mellifera carnica* L., was exposed to **MK 244 05 SG (AI: emamectin benzoate)** for 96 hours in the oral and the contact test. The contact nominal concentrations were 0.0025, 0.005, 0.01, 0.02, and 0.04 µg ai/bee. The actual intake concentrations were 0.00025, 0.0005, 0.001, 0.002, 0.0039, 0.0079, and 0.0157 µg ai/bee. By 96 hours in the oral test, mortality was 10% in the control and 7, 3, 7, 0, 23, 73, and 87% in the treated groups, respectively. There were no reported sublethal effects. By 96 hours in the contact test, mortality was 7% in the control and 47, 83, 90, 100, and 100% in the treated groups, respectively. Apathy and immobility were observed in the treatment groups.

The 96-hour LC_{50} value for the oral test was 0.0063 µg ai/bee, which is equivalent to 0.133 µg form/bee. The 96-hour LD_{50} value for the contact test was 0.0028 µg ai/bee, which is equivalent to 0.0589 µg form/bee. As a result, MK 244 05 SG (AI: emamectin benzoate) is categorized as highly toxic to honey bees *on an acute contact basis.* The 96-hour NOAELs for the oral and contact tests were 0.0039 and <0.0025 µg ai/bee, respectively, which are equivalent to 0.0821 and <0.0526 µg form/bee.

This study is scientifically *sound.* **This study is classified as *ACCEPTABLE.***

Reported Statistical Results - Oral Test:

48-hour
LC_{50}: 0.0068 µg ai/bee 95% C.I.: 0.0056 to 0.0085 µg ai/bee
NOAEL: 0.002 µg ai/bee Probit Slope: 3.02 (2.19-3.85)
LOAEL: 0.0039 µg ai/bee

96-hour
LC_{50}: 0.0063 µg ai/bee 95% C.I.: 0.0053 to 0.0076 µg ai/bee
NOAEL: 0.0039 µg ai/bee Probit Slope: N/A
LOAEL: 0.0079 µg ai/bee

Reported Statistical Results - Contact Test:

48-hour
LD_{50}: 0.0048 µg ai/bee 95% C.I.: 0.0039 to 0.0058 µg ai/bee
NOAEL: 0.0025 µg ai/bee Probit Slope: 3.78 (2.60-4.96)
LOAEL: 0.005 µg ai/bee

96-hour
LD_{50}: 0.0028 µg ai/bee 95% C.I.: 0.0017 to 0.0036 µg ai/bee
NOAEL: <0.0025 µg ai/bee Probit Slope: 2.75 (1.63-3.87)
LOAEL: 0.0025 µg ai/bee

9. ADEQUACY OF THE STUDY:

A. Classification: Acceptable for a formulation

B. Rationale:

C. Repairability:

10. GUIDELINE DEVIATIONS: This study was conducted according to OECD 213 (Honeybees, Acute Oral Toxicity Test) and OECD 214 (Honeybees, Acute Contact Toxicity Test). The reviewer assessed the methods according to OPPTS 850.3020 (Honey Bee Acute Contact Toxicity) and OECD 213/214. Similarities and/or differences were described. Deviations were noted:

1. The study author did not report physical-chemical properties of the test material other than water solubility; OECD guidelines 213 and 214 suggest that these parameters be included.

2. The age of the bees was not reported; OPPTS guidelines suggest that worker bees be 1 to 7 days old at test initiation. However, OECD guidance only suggests that worker bees be young.

3. The oral and contact toxicity tests were conducted for up to 96 hours; OPPTS guidelines suggest 48 hours. However, OECD guidelines suggest a duration of 96 hours if a prolonged observation period is required. In addition, this study measured mortality at 24, 48, 72 and 96 hours.

4. In the contact test, only a control with the dispersant was tested; OPPTS and OECD guidelines require an accompanying negative control.

11. SUBMISSION PURPOSE: The purpose of this study was to determine the acute toxicity of the test material to the honeybee in a laboratory test after oral and contact exposure.

12. MATERIALS AND METHODS:

A. Test Organisms

Guideline Criteria	Reported Information
Species: Species of concern (*Apis mellifera, Megachile rotundata,* or *Nomia melanderi*)	*Apis mellifera carnica* L.
Age at beginning of test:	Not reported – worker bees
Supplier:	Mr. Kern, Leipziger Str.116, D-04420, Leipzig, Germany
All bees from the same source?	Yes; all bees cam from healthy, disease-free and queen-right bee colonies.

B. Test System

Guideline Criteria	Reported Information
Cage size adequate?	Disposable cardboard cage with holes in the bottom for ventilation and a glass plate in front for observation (inside dimensions: 80 x 45 x 65 mm)
Lighting:	Continuous darkness except during treatment administration and observations (diffuse artificial light at 100 lux)
Temperature:	24-26°C
Relative humidity:	55-75%

C. Test Design

Guideline Criteria	Reported Information

Guideline Criteria	Reported Information
Range finding test?	Yes; two range-finding tests were conducted: Contact – 100% mortality after 24 hours Oral – 100% mortality after 24 hours
Reference toxicant test?	Yes; Dimethoate EC 400 (AI: Dimethoate)
Method of administration:	Oral test: bees were fed a 50% aqueous sucrose solution containing the test material via feeding tubes Contact test: bees were anesthetized with CO_2 before the application of 5 µL of the test material in 0.1% v/v Tween on the dorsal thorax via a micropipette
Nominal doses:	Oral test: Not reported; only actual doses reported: 0.00025,0.0005, 0.001, 0.002, 0.0039, 0.0079, and 0.0157 µg ai/bee Contact test: 0.0025, 0.005, 0.01, 0.02, and 0.04 µg ai/bee
Controls: Negative control and/or diluent/solvent control	Oral test: 50% aqueous sucrose solution Contact test: 0.1% v/v Tween solution
Number of colonies per group:	Oral test: 10 bees per cage, 3 reps per treatment group Contact test: 10 bees per cage, 3 reps per treatment group
Solvent: The following solvents: acetone, dimethylformamide, triethylene glycol, methanol, ethanol.	Oral test: N/A Contact test: N/A

Guideline Criteria	Reported Information
Feeding:	Oral test: bees were fed 50% w/v sucrose solution Contact test: bees were fed 50% w/v sucrose solution
Observation period(s):	Oral test: 4, 24, 48, 72, and 96 hours Contact test: 4, 24, 48, 72, and 96 hours

13. REPORTED RESULTS:

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes. This study was conducted in compliance with the Principles of Good Laboratory Practice as described in Attachment 1 to the Chemicals Act of the Federal Republic of Germany (1994) and in consideration of OECD GLP (1997).
Control performance:	Oral test: 0% mortality at 48 hours and 10% mortality at 96 hours Contact test: 7% mortality at 48 and 96 hours
Raw data included:	Yes
Signs of toxicity (if any) were described?	There were no signs of toxicity reported, but the study author did perform observations for potential sublethal effects.

DP Barcode: 381025 MRID No.: 48257501

Mortality - Oral Test

Dosage µg ai/bee (actual intake)	No. of bees	Percent Mortality (%)			
		Hour of Study			
		24	48	72	96
Test Substance					
Negative Control	30	0	0	3	10
0.00025	30	0	0	0	7
0.0005	30	0	0	0	3
0.001	30	3	3	3	7
0.002	30	0	0	0	0
0.0039	30	3	20	20	23
0.0079	30	43	67	72	73
0.0157	30	80	83	83	87
Toxic Standard					
Control	30	0	0	3	10
0.08	30	3	3	3	3
0.096	30	10	17	20	20

Dosage µg ai/bee (actual intake)	No. of bees	Percent Mortality (%)			
		Hour of Study			
		24	48	72	96
0.112	30	23	27	27	33
0.136	30	40	43	53	70
0.16	30	63	70	73	87

Observations:
At 24 hours, there was already 80% mortality in the highest test concentration (0.0157 µg ai/bee). By 48 hours, mortality was 83% in this treatment group, and by 96 hours, mortality was 87%. No sublethal effects were described. The resulting 48 and 96 hour LC_{50} values were 0.0068 µg ai/bee. Apathy and immobility were observed in the treatment groups.

Mortality - Contact Test

Dosage µg ai/bee	No. of bees	Percent Mortality (%)			
		Hour of Study			
		24	48	72	96
Test Substance					
Tween Control	30	3	7	7	7
0.0025	30	7	23	30	47
0.005	30	37	50	63	83
0.01	30	50	90	90	90
0.02	30	90	100	100	100
0.04	30	100	100	100	100
Toxic Standard					
Acetone Control	30	3	7	7	10
0.0125	30	3	10	17	23
0.025	30	10	20	27	33
0.05	30	13	27	37	47

Dosage µg ai/bee	No. of bees	Percent Mortality (%)			
		Hour of Study			
		24	48	72	96
0.1	30	20	30	43	53
0.2	30	663	73	83	93

Observations:
At 24 hours, there was already 100% mortality in the highest test concentration (0.04 µg ai/bee). No sublethal effects were described. The resulting 48 and 96 hour LD_{50} values were 0.0048 and 0.0027 µg ai/bee, respectively. Apathy and immobility were observed in the treatment groups.

Statistical method: The mortality data were analyzed using either the Dunnett t-test or the U-test after Bonferroni-Holm was used ($p \leq 0.05$; one-sided smaller). The LC/LD_{50} values were calculated by Probit analysis according to the maximum likelihood method. The goodness-of-fit of the mode evaluated using Pearson's chi-squared test. The analyses were performed using EASY ASSAY by Ratte (1998).

Reported Statistical Results - Oral Test:

48-hour
LC_{50}: 0.0068 µg ai/bee 95% C.I.: 0.0056 to 0.0084 µg ai/bee
NOAEL: Not determined Probit Slope: 3.014
LOAEL: Not determined

96-hour
LC_{50}: 0.0068 µg ai/bee 95% C.I.: 0.0055 to 0.0084 µg ai/bee
NOAEL: Not determined Probit Slope: 3.559
LOAEL: Not determined

Reported Statistical Results - Contact Test:

48-hour
LD_{50}: 0.0048 µg ai/bee 95% C.I.: 0.0039 to 0.0059 µg ai/bee
NOAEL: Not determined Probit Slope: 3.573
LOAEL: Not determined

96-hour
LD_{50}: 0.0027 µg ai/bee 95% C.I.: 0.0018 to 0.0039 µg ai/bee
NOAEL: Not determined Probit Slope: 2.483
LOAEL: Not determined

14. VERIFICATION OF STATISTICAL RESULTS:

Statistical method: Mortality data were analyzed to determine LC/LD_{50} values using Toxanal 2009. The 48-hour oral toxicity test data were analyzed using the Probit analysis, which had a goodness of fit probability of 0.222 for the 48 hour test. The 96-hour oral toxicity test data were analyzed using the moving average method due to the probit method not being suitable for analysis (the goodness of fit probability was less than 0.001). The 48-hour and 96-hour contact toxicity test data were analyzed using the Probit analysis, which had a goodness of fit probability of 0.793 and 0.599 for the 48 and 96 hour tests, respectively. The 48- and 96-hour NOAELs were determined using Fisher's Exact Test in Toxstat 3.5.

Results - Oral Test:

48-hour
LC_{50}: 0.0068 µg ai/bee 95% C.I.: 0.0056 to 0.0085 µg ai/bee

NOAEL: 0.002 µg ai/bee
LOAEL: 0.0039 µg ai/bee
Probit Slope: 3.02 (2.19-3.85)

96-hour
LC_{50}: 0.0063 µg ai/bee
NOAEL: 0.0039 µg ai/bee
LOAEL: 0.0079 µg ai/bee
95% C.I.: 0.0053 to 0.0076 µg ai/bee
Probit Slope: N/A

Results - Contact Test:

48-hour
LD_{50}: 0.0048 µg ai/bee
NOAEL: 0.0025 µg ai/bee
LOAEL: 0.005 µg ai/bee
95% C.I.: 0.0039 to 0.0058 µg ai/bee
Probit Slope: 3.78 (2.60-4.96)

96-hour
LD_{50}: 0.0028 µg ai/bee
NOAEL: <0.0025 µg ai/bee
LOAEL: 0.0025 µg ai/bee
95% C.I.: 0.0017 to 0.0036 µg ai/bee
Probit Slope: 2.75 (1.63-3.87)

15. REVIEWER'S COMMENTS:

The reviewer's and the study author's results were very similar; however, the reviewer also calculated NOAEL and LOAEL values. The reviewer's results are presented in the Executive Summary and Conclusion sections of this DER.

The 48-hour oral and contact LD_{50} and LD_{50} values were equivalent to 0.143 and 0.101 µg test item/bee, respectively.

16. REFERENCES:

Abbott, W.S.: A method of computing the effectiveness of an insecticide. J. Econ. Entomol. 18, 265-267, 1925.

Chemikaliengesetz der Bundesrepublik Deutschland in der Neufassung vom 20. Juli 1994, Anhang 1. BGBI. Teil I, Nr. 40, S.1703; letzte Anderung vom 14. Mai 1997, BGBI Teil I, Nr. 30, S. 1060.

Finney, D.J.: Probit Analysis, 3rd Edition. London: Cambridge University Press, 1971.

EPPO Guideline for the efficacy evaluation of plant protection products PP 1/170(2): Side-

effects on honeybees. EPPO Standards, Vol. I, 161-164, 1999.

OECD Principles of Good Laboratory Practice (as revised in 1997). ENV/MC/CHEM(98)17.

OECD Guidelines for the Testing of Chemicals 213 (adopted 21st September 1998): Honeybees, Acute Oral Toxicity Test. ENV/EPOC(98)9.

OECD Guidelines for the Testing of Chemicals 214 (adopted 21st September 1998): Honeybees, Acute Contact Toxicity Test. ENV/EPOC(98)9.

Ratte, H.T.: EASY ASSAY, *Critical Values*, Ver. 3.01; Multiple Testing, Ver. 4.0. SpiRiT, Aachen 1998.

SETAC: Procedures for assessing the environmental fate and ecotoxicity of pesticides. SETAC Europe, 1995.

Appendix I. Statistics Verified by the Reviewer

48-HOUR ORAL TEST

Moncie Wright Emamectin Benzoate Acute

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CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
.0157	30	25	83.33333	1.624572E-02
.0079	30	20	66.66667	4.936858
.0039	30	6	20	7.154533E-02
.002	30	0	0	9.313227E-08
.001	30	1	3.333334	2.8871E-06
.0005	30	0	0	9.313227E-08
.00025	30	0	0	9.313227E-08

THE BINOMIAL TEST SHOWS THAT .0039 AND .0157 CAN BE
USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT
CONFIDENCE LIMITS, BECAUSE THE ACTUAL CONFIDENCE LEVEL
ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 6.186292E-03

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
3	5.636698E-02	6.866329E-03		5.718356E-03
	8.456758E-03			

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
5	7.564333E-02	1	.2223545

SLOPE = 3.019819
95 PERCENT CONFIDENCE LIMITS = 2.189268 AND 3.85037

INTERCEPT= 6.539934

LC50 = 6.828564E-03
95 PERCENT CONFIDENCE LIMITS = 5.581073E-03 AND 8.543959E-03

LC25 = 4.082927E-03
95 PERCENT CONFIDENCE LIMITS = 3.122502E-03 AND 5.018829E-03

LC10 = 2.569999E-03
95 PERCENT CONFIDENCE LIMITS = 1.731888E-03 AND 3.323575E-03

LC05 = 1.948176E-03
95 PERCENT CONFIDENCE LIMITS = 1.20047E-03 AND 2.633136E-03
*

Summary of Fisher's Exact Tests

GROUP	IDENTIFICATION	NUMBER EXPOSED	NUMBER DEAD	SIG 0.05
	CONTROL	30	0	
1	0.00025	30	0	
2	0.0005	30	0	

3	0.001	30	1	
4	0.002	30	0	
5	0.0039	30	6	*
6	0.0079	30	20	*
7	0.0157	30	25	*

96-HOUR ORAL TEST

NOTE: THERE WAS CONTROL MORTALITY, BUT AT LEAST ONE
OF THE LOWER CONCENTRATIONS HAD ZERO MORTALITY.
THEREFORE, ABBOTT'S CORRECTION IS NOT APPLICABLE.

Moncie Wright Emamectin Benzoate Oral

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
.0157	30	26	86.66666	2.973807E-03
.0079	30	22	73.33334	.8062402
.0039	30	7	23.33334	.261144
.002	30	0	0	9.313227E-08
.001	30	2	6.666667	4.339964E-05
.0005	30	1	3.333334	2.8871E-06
.00025	30	2	6.666667	4.339964E-05

THE BINOMIAL TEST SHOWS THAT .0039 AND .0079 CAN BE
USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT
CONFIDENCE LIMITS, BECAUSE THE ACTUAL CONFIDENCE LEVEL
ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 5.695544E-03

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
3	.0518449	6.274079E-03	5.262879E-03	7.580289E-03

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
4	.8817627	7.744642	0

A PROBABILITY OF 0 MEANS THAT IT IS LESS THAN 0.001.

SINCE THE PROBABILITY IS LESS THAN 0.05, RESULTS CALCULATED
USING THE PROBIT METHOD PROBABLY SHOULD NOT BE USED.

SLOPE = 1.908259
95 PERCENT CONFIDENCE LIMITS = .1163614 AND 3.700156

INTERCEPT= 4.260535

LC50 = 5.852186E-03
95 PERCENT CONFIDENCE LIMITS = 1.59956E-03 AND 5.982825

LC25 = 2.593309E-03
95 PERCENT CONFIDENCE LIMITS = 1.154296E-06 AND 8.703721E-03

LC10 = 1.246553E-03
95 PERCENT CONFIDENCE LIMITS = 1.252393E-11 AND 3.333069E-03

LC05 = 8.04133E-04

95 PERCENT CONFIDENCE LIMITS = 1.056003E-14 AND 2.379945E-03
****

Summary of Fisher's Exact Tests

GROUP	IDENTIFICATION	NUMBER EXPOSED	NUMBER DEAD	SIG 0.05
	CONTROL	30	3	
1	0.00025	30	2	
2	0.0005	30	1	
3	0.001	30	2	
4	0.002	30	0	
5	0.0039	30	7	
6	0.0079	30	22	*
7	0.0157	30	26	*

48-HOUR CONTACT TEST

NOTE: BECAUSE THERE WAS CONTROL MORTALITY, AND NONE
OF THE LOWER CONCENTRATIONS PRODUCED ZERO MORTALITY,
THE DATA HAS BEEN SUBJECTED TO ABBOTT'S CORRECTION.

Moncie Wright Emamectin Benzoate Contact
****

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
.04	28	28	100	3.72529E-07
.02	28	28	100	3.72529E-07
.01	28	25	89.2857	1.372025E-03
.005	28	13	46.4286	42.52771
.0025	28	5	17.8571	4.561172E-02

THE BINOMIAL TEST SHOWS THAT .0025 AND .01 CAN BE
USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT
CONFIDENCE LIMITS, BECAUSE THE ACTUAL CONFIDENCE LEVEL
ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 5.263555E-03

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
2	.1146794	4.938979E-03	3.972795E-03	6.120636E-03

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
5	9.789671E-02	1	.7925791

SLOPE = 3.781047
95 PERCENT CONFIDENCE LIMITS = 2.598016 AND 4.964079

INTERCEPT= 8.772449

LC50 = 4.785079E-03
95 PERCENT CONFIDENCE LIMITS = 3.891554E-03 AND 5.77065E-03

LC25 = 3.173215E-03

95 PERCENT CONFIDENCE LIMITS = 2.315924E-03 AND 3.90055E-03

LC10 = 2.192479E-03
95 PERCENT CONFIDENCE LIMITS = 1.393245E-03 AND 2.856576E-03

LC05 = 1.75732E-03
95 PERCENT CONFIDENCE LIMITS = 1.020053E-03 AND

Summary of Fisher's Exact Tests

GROUP	IDENTIFICATION	NUMBER EXPOSED	NUMBER DEAD	SIG 0.05
	CONTROL	30	2	
1	0.0025	30	7	
2	0.005	30	15	*
3	0.01	30	27	*
4	0.02	30	30	*
5	0.04	30	30	*

96-HOUR CONTACT TEST

NOTE TO REVIEWER: THIS DATA SET DOES NOT MEET
THE CRITERIA ESTABLISHED BY THE COMMITTEE ON METHODS
FOR TOXICITY TESTS WITH AQUATIC ORGANISMS BECAUSE
NO PERCENT DEAD IS LESS THAN 35 PERCENT.
NOTE: BECAUSE THERE WAS CONTROL MORTALITY, AND NONE
OF THE LOWER CONCENTRATIONS PRODUCED ZERO MORTALITY,
THE DATA HAS BEEN SUBJECTED TO ABBOTT'S CORRECTION.

Moncie Wright Emamectin Benzoate Contact

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB.(PERCENT)
.04	28	28	100	3.72529E-07
.02	28	28	100	3.72529E-07
.01	28	25	89.2857	1.372025E-03
.005	28	23	82.1429	4.561172E-02
.0025	28	12	42.8571	28.57942

THE BINOMIAL TEST SHOWS THAT 0 AND .005 CAN BE
USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT
CONFIDENCE LIMITS, BECAUSE THE ACTUAL CONFIDENCE LEVEL
ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 2.814944E-03

RESULTS CALCULATED USING THE MOVING AVERAGE METHOD

SPAN	G	LC50	95 PERCENT CONFIDENCE LIMITS	
1	.4120646	2.814944E-03	1.637147E-03	3.516417E-03

RESULTS CALCULATED USING THE PROBIT METHOD

ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
4	.1664497	1	.5994003

SLOPE = 2.750642
95 PERCENT CONFIDENCE LIMITS = 1.628428 AND 3.872855

INTERCEPT= 7.036519

LC50 = 2.766066E-03
95 PERCENT CONFIDENCE LIMITS = 1.736502E-03 AND 3.620776E-03

LC25 = 1.572705E-03
95 PERCENT CONFIDENCE LIMITS = 7.082961E-04 AND 2.290328E-03

LC10 = 9.460953E-04
95 PERCENT CONFIDENCE LIMITS = 3.065847E-04 AND 1.563115E-03

LC05 = 6.980022E-04
95 PERCENT CONFIDENCE LIMITS = 1.848161E-04 AND 1.24996E-03

Summary of Fisher's Exact Tests

GROUP	IDENTIFICATION	NUMBER EXPOSED	NUMBER DEAD	SIG 0.05
	CONTROL	30	2	
1	0.0025	30	14	*
2	0.005	30	25	*
3	0.01	30	27	*
4	0.02	30	30	*
5	0.04	30	30	*

Recommendation of Division Directors **EMAMECTIN**

Negotiated Due Dates **TREE INJECTION**
EXPAND TREE SPECIES

Decision#: D427963	**Registration 100-1309**	**Petition #: ---**
Fee Category: R350	**PRIA Decision Time Frame: 8 months**	
Submitted by: Tom Harris	**Branch: RD/IRB**	**Date: 11/3/2010**
Company: Syngenta Crop Protection, Inc.		
Original Due Date: 11/5/2010	**Proposed New Due Date: 12/17/2010**	
Previous Negotiated Due Dates: no		
Is the "Fix" in-house? yes	**If not, date "Fix" expected: n/a**	

Issue (describe in detail):

Emamectin tree injection product was first registered 7/11/09 but limited to ash trees only for emerald ash borer due to uncertainty concerning pollinator effects. On 11/13/09 a 2-year efficacy claim was substantiated and added to label. On 2/10/10 Syngenta submitted an amendment to expand from ash trees only to many ornamental trees for many pests. Application included a pollinator risk assessment plus a study on residues in pollen of cherry trees; both were sent to EFED for review. Additional information was requested by EFED in July (analytical methods) and September (chromatograms from pollen study). In early October EFED requested a bee acute toxicity study which was referenced in the pollinator risk assessment but had not been submitted on it's own. Study was submitted and sent to EFED. Note: advanced e-copy of study sent to EFED 10/4/10; paper copy forwarded to EFED 10/29/10 when it was finally received by PM.

While registrant has been very responsive to requests for information the fact still remains that key information was submitted well after initial application, indeed up to just a month before the PRIA date for the bee acute tox study. That study has been sent to contractor for primary review. An extension of the due date is needed to complete primary and secondary review of the bee acute tox study and to incorporate the results into the EFED decision memo.

Summary of Deficiency Type(s): **Not Submitted (N)** **Deficiencies (D)**
Product Chemistry: ___ Acute Tox: ___ Efficacy: ___ Labeling: ____ Other?: _X_ eco tox

Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):

Phone calls and emails. See attached 11/3/10 email from Syngenta accepting a 90-day extension. Agency will only need half of that and so will leave 12/17/2010 as negotiated due date.

"75 Day" Letter sent? _____ (Date sent)Yes __X__No and reason for none? Not applicable.

Rationale for Proposed Due Date:

Need moderate extension to complete review of data (bee acute toxicity) submitted a month before PRIA due date.

Registrant notified that this is the last negotiation? _____Yes _X__Not Applicable

Approve: ✓	**Disapprove:**

If disapproved, action to be taken:

OD or DOD Signature: WRD	**Date:** 11.4.10

Revised May 2007

RE: Emamectin Tree Injection, # 100- 1309 expand tree species
Thomas Harris to: tom.parshley 11/03/2010 02:15 PM
Cc: carolyn.brinkley, John Hebert

This email chain is sufficient; I do not need a formal letter regarding the negotiated date.

Note that while you agreed to a 90-day extension we only need half that. I'll leave the negotiated date at 12/17/10.

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

Tom: Syngenta agrees to the additional 90 days... 11/03/2010 01:18:08 PM

From:	<tom.parshley@syngenta.com>
To:	Thomas Harris/DC/USEPA/US@EPA
Cc:	John Hebert/DC/USEPA/US@EPA, <carolyn.brinkley@syngenta.com>
Date:	11/03/2010 01:18 PM
Subject:	RE: Emamectin Tree Injection, # 100- 1309 expand tree species

Tom: Syngenta agrees to the additional 90 days to the PRIA due date for this action. If you want a formal letter, let me know.

Tom Parshley

-----Original Message-----
From: harris.thomas@epamail.epa.gov [mailto:harris.thomas@epamail.epa.gov]
Sent: Monday, November 01, 2010 2:19 PM
To: Parshley Tom USGR
Cc: Hebert.John@epamail.epa.gov
Subject: RE: Emamectin Tree Injection, # 100- 1309 expand tree species

Tom,

EFED is still working away at your data to support expanding the tree species on the emamectin tree injection. Given that the acute bee tox study was just submitted the beginning of October I need to ask if you would agree to negotiate the PRIA due date for this action. This study was referenced in the pollinator risk assessment submitted with your application for amendment but the study itself was not submitted at that time.

An electronic copy of the bee study was sent to our contractor for primary review in early October when you emailed it to me. The paper copy just arrived on my desk last week but that didn't hold anything up; we just need to MRID from that process to include in the reviews. Once the contractor is done, the study then needs to go back to EFED for secondary review and incorporation into their final risk assessment. EFED has estimated that they should be able to complete their review by Thanksgiving. Adding a little time to that to iron out any labeling issues they turn up, I am proposing a negotiated PRIA date of Friday, 12/17/10.

Please let me know if 12/17/10 is acceptable to Syngenta as a negotiated PRIA due date. Feel free to give me a call if you would like to discuss this action.

Tom Harris

EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

message may contain confidential information. If you are not the designated recipient, please notify the sender immediately, and delete the original and any copies. Any use of the message by you is prohibited.

emamectin tree inject - new PRIA date 12/17/10; can ask for brood tests as condition of registration; no usage data available

Thomas Harris to Pamela Hurley 11/03/2010 02:43 PM

Cc: Dana Spatz, John Hebert

[I'm jumping the gun a little but I'm assuming that Marty will sign the negotiated due date form I just sent up]

The new PRIA due date for this action is now 12/17/10. Per your emails, I will expect the EFED review by Thanksgiving. That actually gives you a little extra time beyond your email estimate.

As discussed below, the review can include any data studies you want them to conduct. Up to you, but we should probably state that they need to do some sort of brood toxicity study. This can be a condition of registration given that we expect exposure to be low to do expense of doing tree injections.

I talked to Syngenta about any usage data they have on tree injection. I'm afraid they can not provide anything quantitative. They did confirm our thinking that use is limited to high value ornamental trees (not forestry or other tree intensive uses) given the high cost of material and treatment.

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

Pamela Hurley I agree. Fruit trees are probably the worst case.... 11/02/2010 09:26:44 AM

From: Pamela Hurley/DC/USEPA/US
To: Thomas Harris/DC/USEPA/US@EPA
Date: 11/02/2010 09:26 AM
Subject: Re: emamectin tree inject - can ask for brood tests as condition of registration

I agree. Fruit trees are probably the worst case. I am wondering if they have more residue data on cherry trees than they have submitted. The analytical method was validated for determination of residues in tree parts (xylem, phloem, foliage and pollen).

Just so that I know whether or not to wait for a Registrant response in order to finish this assessment, are you going to ask them if they have an idea of the extent of the usage for emamectin? If they do have an idea of the usage and it is relatively low, we may not have to ask for additional data. I have discussed this with Tom Steeger and he agrees that.

Pam

Thomas Harris Pam, Thanks for your help with how to handle th... 11/01/2010 05:19:08 PM

From: Thomas Harris/DC/USEPA/US
To: Pamela Hurley/DC/USEPA/US@EPA
Date: 11/01/2010 05:19 PM
Subject: emamectin tree inject - can ask for brood tests as condition of registration

Pam,

Thanks for your help with how to handle the emamectin tree injection. Assuming we get through the negotiated due date and your bee data looks ok we will probably go ahead and accept the amendment to expand tree species. A couple of caveats:

1) If there are any tree species where the exposure might be especially bad for bees let me know and I

can block those. I think everyone is thinking cherry trees (on which they submitted data) would be a worst case with high exposure so if cherries are ok then there may not be any other trees to worry about. Just checking.

2) Given that the effect on brood is an uncertainty, we may want to consider requiring some studies as a condition of registration. We did a DCI for brood studies using imidacloprid tree injection so it would make sense to do the same for emamectin (fortunately it's just one registrant so we don't need to do a DCI). Just give me a guideline #, title, and length of time (i.e. due date) for each study. Talk with Tom Steeger about what to ask for.

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

100-1309 Emamectin Tree Injection
Regulatory History

date	action	comments
7/11/09	D387891 - original registration accepted	limited to ash trees only for emerald ash borer
11/13/09	D421584 - amendment to add 2-year efficacy claim accepted	
2/10/10	D427963 - amendment to expand from ash trees only to many ornamental trees data: Syngenta pollinator risk assessment	also - data: effect on cherry tree pollen this was submitted very late in original registration application and held pending amendment to expand sites
7/29/10	data: analytical method info requested by EFED 7/23/10	
9/14/10	data: chromatograms for pollen analysis requested by EFED 9/4/10	*advanced email e-copy of data sent to EFED on 9/9/10*
10/7/10	data: acute bee tox requested by EFED 10/4/10	study is referenced in Syngenta risk assessment but not submitted by itself e-copy study sent to contractor *advanced email e-copy of data sent to EFED on 10/4/10)*

volume of use for tree injection applications (rm 7731)
Calendar Entry
Wed 10/06/2010 1:30 PM - 2:00 PM
Rooms: RD Small Conference Room E (S-7731)/Potomac Yard One@EPA

Required:	Donald Atwood/DC/USEPA/US@EPA, Pamela Hurley/DC/USEPA/US@EPA, TJ Wyatt/DC/USEPA/US@EPA
Optional:	Arnet Jones/DC/USEPA/US@EPA

Description

EFED is doing a review of emamectin as an injection on ornamental trees. Given focus on pollinators, we are concerned with exposure to bees via pollen (especially since this particular product stays effective for two years). However, it is possible that tree injection (all chemicals and/or emamectin alone) is so limited that risk to populations of pollinators may also be low. Also, it may not be worth the expense of figuring out injection risk relative to more common foliar spray applications. EFED would like to discuss whatever you know or can find about usage of tree injection as an application method for emamectin or all chemicals in general.

- ? ema detect from ag on bee hives?
- DPR found limited info on tree inject; no usage

Venus, Mered. ? RD pollinator team
Clayton

Action items

PH - write list of questions/issues
TH - forward list to Sqn
PH - talk to Tom Steger/Priority - to look at general pesticide residues in bee hive studies. Any emamectin or avermectin residues? Extrapolate to ema use.
PH - look for any avermectin hive studies, extrapolate to ema use

Memorandum

Date: **10/22/10**

To: **PM 7**, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:
- ☒ **fully accepted submission**
- ☐ partially accepted submission
- ☐ rejected submission

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 15, 2010

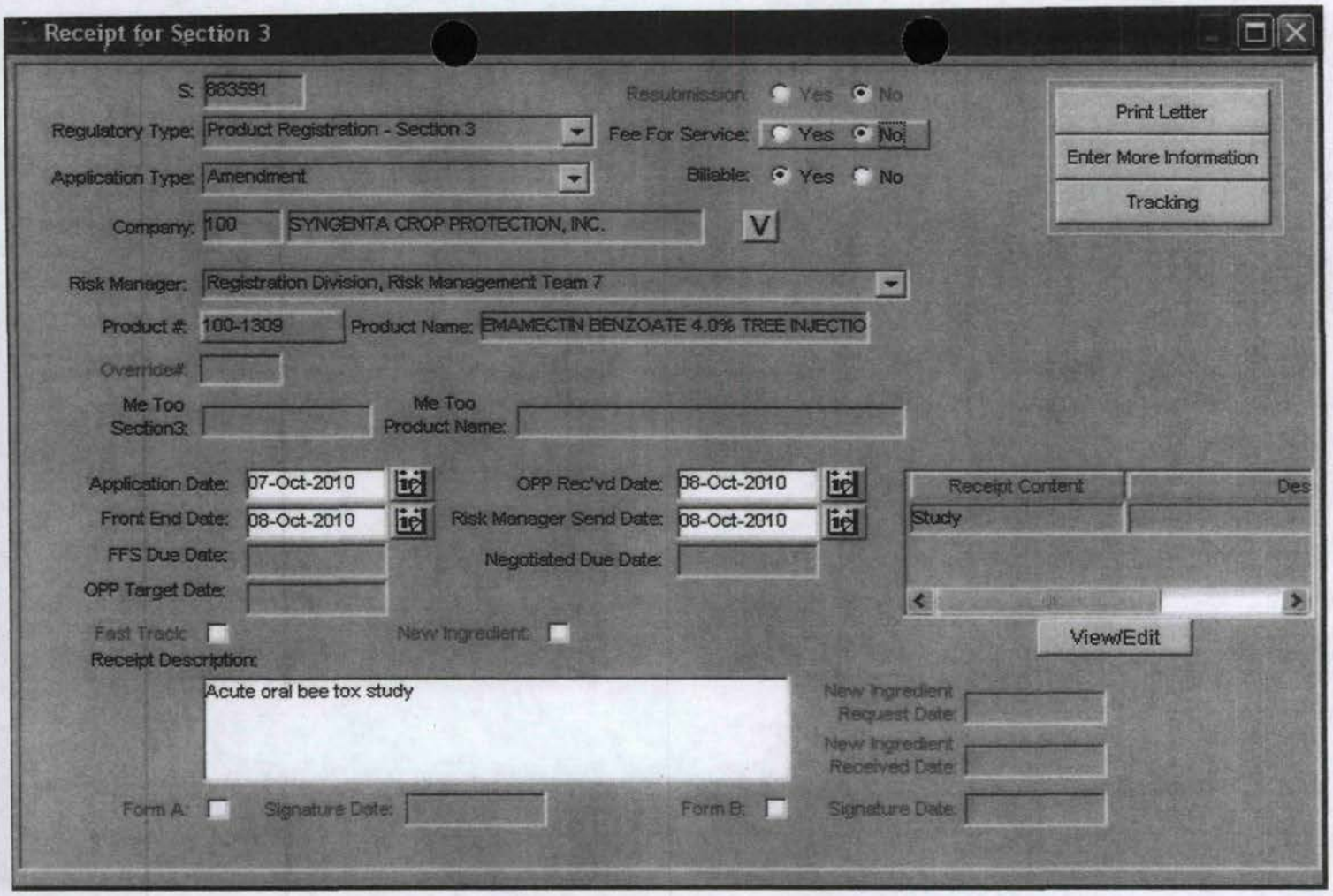
OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SYNGENTA CROP PROTECTION, INC.
ATTN: REGULATORY AFFAIRS
PO Box 18300
GREENSBORO, NC 27419-8300

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 08-OCT-10. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.


Receipt for Section 3
S: 863591
Resubmission: Yes No
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: Amendment
Billable: Yes No
Company: 100 SYNGENTA CROP PROTECTION, INC.
Print Letter
Enter More Information
Tracking
Risk Manager: Registration Division, Risk Management Team 7
Product #: 100-1309
Product Name: EMAMECTIN BENZOATE 4.0% TREE INJECTIO
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 07-Oct-2010
OPP Rec'vd Date: 08-Oct-2010
Front End Date: 08-Oct-2010
Risk Manager Send Date: 08-Oct-2010
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Des
Study
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
Acute oral bee tox study
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

482575-00

Thomas J. Parshley
Senior Regulatory Product Manager
Syngenta Regulatory Affairs
Lawn and Garden Products
(336) 632-7207 (phone)
(336) 632-5688 (fax)
tom.parshley@syngenta.com

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syngenta

FedEx

October 7, 2010

Document Processing Desk
Office of Pesticide Programs (**7504P**)
U.S. Environmental Protection Agency
2777 South Crystal Drive
Room S-4900, One Potomac Yard
Arlington, VA 22202-4501

Attention: **Mr. Thomas Harris**

SUBJECT: ***EPA REVIEWER REQUEST FOR ACUTE ORAL BEE STUDY TO SUPPORT REQUEST TO EXPAND TREE SPECIES FOR EMAMECTIN BENZOATE 4.0% TREE INJECTION, EPA REG NO. 100-1309***

Dear Mr. Harris:

Enclosed please find the following information in support of the subject request:

- Transmittal document
- One (1) data volume containing the subject information.

The pending amendment action is an ongoing PRIA action and the fee for this action has already been paid. The enclosed additional information was requested by your office in an e-mail dated October 4, 2010, and our e-mail response was dated October 4, 2010 (copies enclosed).

Please contact me at (336) 632-7207 if there are any questions concerning this submission or the subject pending registration action.

Sincerely,

Thomas J Parshley

Thomas J. Parshley
NAFTA Senior Regulatory Product Manager
Syngenta Regulatory Affairs

Enclosed data submission

VOLUME 1 OF 2 OF SUBMISSION
(TRANSMITTAL DOCUMENT)

1. Name and Address of Submitter

Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, NC 27419

2. Regulatory Action in Support of which this Package is Submitted

EPA Reviewer Request for Acute Oral Bee Study to Support Request to Expand Tree Species for Emamectin Benzoate 4.0% Tree Injection, EPA Reg. No. 100-1309.

3. Transmittal Date

10/07/2010

4. List of Submitted Studies

MRID NUMBER	VOLUME NUMBER	STUDY TITLE	EPA GUIDELINE NUMBER
	1 OF 2	Transmittal Document	N/A
48257501	2 OF 2	Acute Toxicity of MK 244 05 SG (A-10324 A) to the Honeybee Apis mellifera L. Under Laboratory Conditions, 01 10 48 027, (A10324A_50004)	850.3020

COMPANY OFFICIAL THOMAS J. PARSHLEY (NAME) — Thomas J Parshley (SIGNATURE)

COMPANY NAME: SYNGENTA CROP PROTECTION

COMPANY CONTACT: THOMAS J. PARSHLEY (NAME) — (336) 632-7207 (PHONE)

Parshley Tom USGR

From: harris.thomas@epamail.epa.gov
Sent: Monday, October 04, 2010 2:44 PM
To: Parshley Tom USGR
Subject: RE: Emamectin Injection question: acute oral bee study

Tom,

Thanks for the fast response! Excellent.

I've sent it on to EFED. I think they'll be amazed since they just sent me the question this morning. I'll look for the formal MRID version (but I won't hold my breath; unlike you, we seem to take a while to get paperwork processed). I told EFED to just leave a placeholder for the MRID #.

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

From: <tom.parshley@syngenta.com>

To: Thomas Harris/DC/USEPA/US@EPA

Date: 10/04/2010 02:24 PM

Subject: RE: Emamectin Injection question: acute oral bee study

Tom: Here is an electronic version of the study that was cited in the risk assessment. I failed to realize this study had not already been submitted to EPA prior to the risk assessment being submitted or I would have provided it with the risk assessment; my apologies for that oversight. I would note the study is not fully in EPA required submission format yet as far as the title page is concerned, but wanted you to have an electronic version right away right out of our data archive system in Europe. I will submit the official paper copy through normal channels as soon as we can get it done, probably later this week. Hopefully EFED will take the enclosed PDF version and use it for their review to keep the process moving. Let me know if this approach is ok.

Best regards,

Tom

-----Original Message-----
From: harris.thomas@epamail.epa.gov [

mailto:harris.thomas@epamail.epa.gov]
Sent: Monday, October 04, 2010 11:11 AM
To: Parshley Tom USGR
Subject: Emamectin Injection question: acute oral bee study

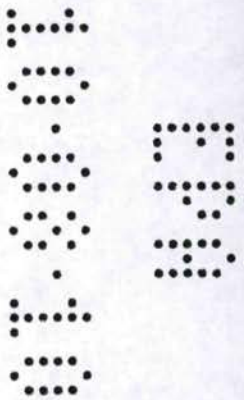
Tom,

EFED is looking at the studies you submitted to support expanding use of Emamectin Benzoate 4% Tree Injection and they have another question.
Syngenta based the assessment of risk for honeybees on an acute oral study with bees that we can't find in the EPA MRID records. It is referenced in your risk assessment for bees (MRID 477674-01) page 6 of
15 near the top (Barth 2001). Then, it is the first reference in the reference section on page 7 of 15. The reference is Barth M. 2001, Acute toxicity of MK 244 05 SG (A-10324 A) to the honeybee, Apis mellifera L., under laboratory conditions, Syngenta project number 2002659.

Was this acute oral bee study submitted to EPA? If so, please give me the MRID and I'll be able to find it. If not, could it be? Thanks.

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

message may contain confidential information. If you are not the designated recipient, please notify the sender immediately, and delete the original and any copies. Any use of the message by you is prohibited.
[attachment "Acute toxicity to bees.pdf" deleted by Thomas Harris/DC/USEPA/US]



Emamectin Injection question: acute oral bee study

Thomas Harris to tom.parshley 10/04/2010 11:11 AM

Bcc: Pamela Hurley

Tom,

EFED is looking at the studies you submitted to support expanding use of Emamectin Benzoate 4% Tree Injection and they have another question. Syngenta based the assessment of risk for honeybees on an acute oral study with bees that we can't find in the EPA MRID records. It is referenced in your risk assessment for bees (MRID 477674-01) page 6 of 15 near the top (Barth 2001). Then, it is the first reference in the reference section on page 7 of 15. The reference is Barth M. 2001, Acute toxicity of MK 244 05 SG (A-10324 A) to the honeybee, Apis mellifera L., under laboratory conditions, Syngenta project number 2002659.

Was this acute oral bee study submitted to EPA? If so, please give me the MRID and I'll be able to find it. If not, could it be? Thanks.

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

Re: Fw: Emamectin Benzoate 4% Tree Injection DP 381025; Amendment to Expand Tree Species, EPA Reg. No. 100-

Pamela Hurley to: Thomas Harris 10/04/2010 07:33 AM

It is referenced in their risk assessment for bees (MRID 477674-01) page 6 of 15 near the top (Barth 2001). Then, it is the first reference in the reference section on page 7 of 15. I didn't see any statement that it was never submitted, and yes, I based it on the fact that I couldn't find it in our MRIDs on OPPIN. Usually, when Registrants use a study that has been submitted, they reference the MRID number somewhere in the document. They didn't do that. Could the bee study be listed in OPPIN under a formulation or under some other chemical by accident? Maybe we should ask the Registrant if that study has ever been submitted. I will be talking with a couple of our senior biologists today. I will let you know what they say.

Pam

Thomas Harris | Pam, Thanks for the update. One question: Did... | 10/01/2010 03:28:37 PM

From: Thomas Harris/DC/USEPA/US
To: Pamela Hurley/DC/USEPA/US@EPA
Date: 10/01/2010 03:28 PM
Subject: Re: Fw: Emamectin Benzoate 4% Tree Injection DP 381025; Amendment to Expand Tree Species, EPA Reg. No. 100-

Pam,

Thanks for the update. One question: Did Syngenta reference the acute bee study and say "never submitted" or are you basing that on the fact that you can't find it in our MRIDs?

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

Pamela Hurley | I have been looking at the original EFED risk as... | 10/01/2010 02:44:54 PM

From: Pamela Hurley/DC/USEPA/US
To: Thomas Harris/DC/USEPA/US@EPA
Cc: Dana Spatz/DC/USEPA/US@EPA, James Hetrick/DC/USEPA/US@EPA, Brian Anderson/DC/USEPA/US@EPA
Date: 10/01/2010 02:44 PM
Subject: Re: Fw: Emamectin Benzoate 4% Tree Injection DP 381025; Amendment to Expand Tree Species, EPA Reg. No. 100-

I have been looking at the original EFED risk assessment for this use (D351736) from Brian Anderson and Jim Hetrick, dated 1/13/2009 along with the submitted Syngenta risk assessment. The EFED risk assessment did not have the cherry tree residue data that we now have. BTW, the cherry data from what I can tell is only for pollen, so we don't have any data for leaves or any other part of the tree. So, for mammals and birds, it may end up being the same as before but the staff here will be discussing what to do with birds and mammals with only the pollen data The other issue that Syngenta based their assessment of risk for honeybees on an acute oral study with bees that was never submitted to the Agency. We have an acute contact study and a foliage residue study. We will be discussing whether or not we can assess the risk without that study but if the main route of exposure for the honeybee is consuming the pollen, we may need that acute oral bee study. The reference is Barth M. 2001. Acute toxicity of MK 244 05 SG (A-10324 A) to the honeybee, Apis mellifera L., under laboratory conditions. Syngenta project number 2002659.

Pam

Thomas Harris | Pam, Just checking to see if this analysis is prog... | 09/28/2010 03:19:42 PM

emamectin MRID 482268-01

Thomas Harris to Pamela Hurley

09/29/2010 03:28 PM

Pam,

I just got the paper copy of the emamectin chromatograms. The MRID is 482268-01. I had sent you an electronic copy via 9/9/10. I will not bother to bean this paper MRID to you unless you want me to.

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

Memorandum

Date: 9/23/10

To: PM 7, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:
- ☒ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission

... On the 21 day
room

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 21, 2010

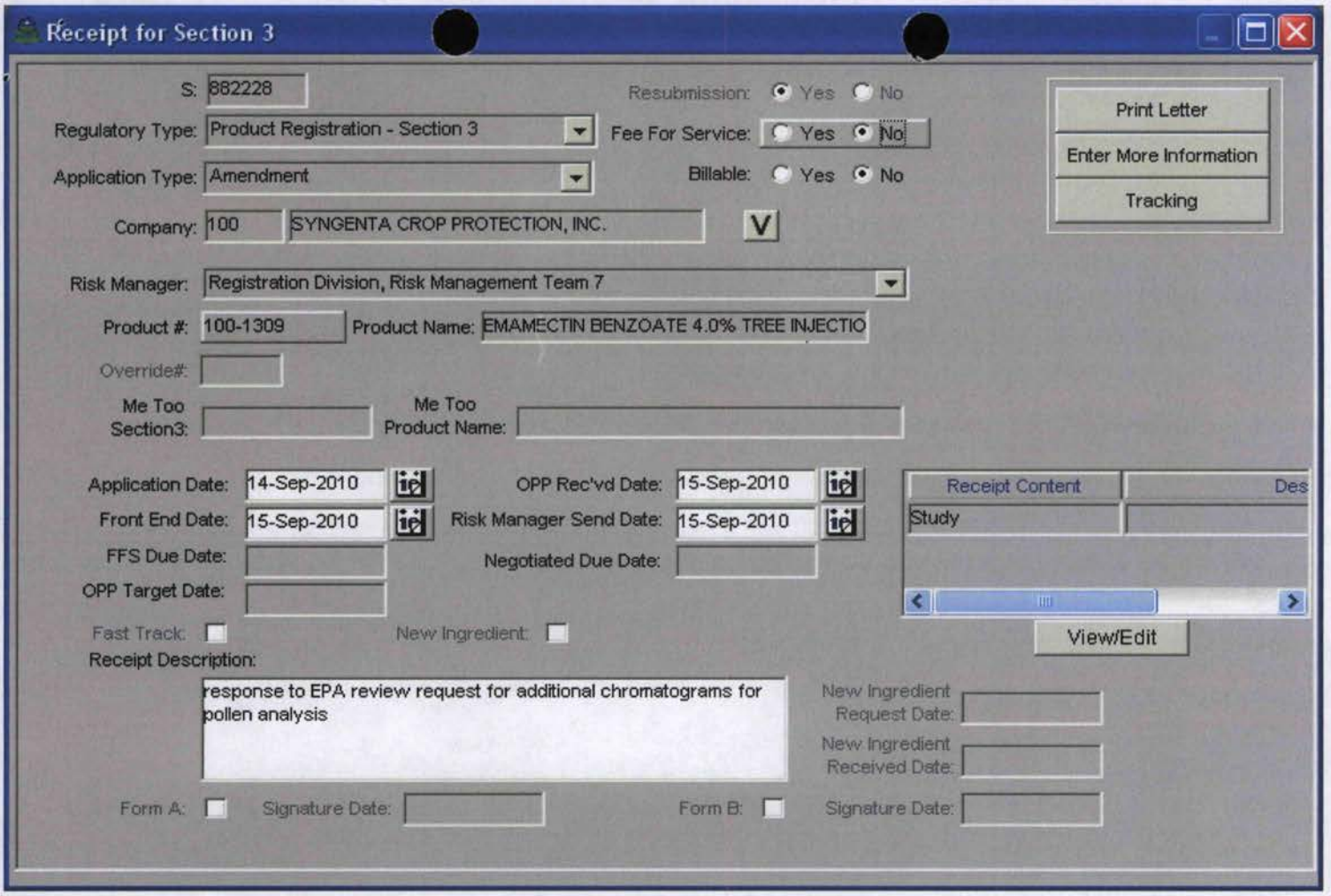
OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SYNGENTA CROP PROTECTION, INC.
ATTN: REGULATORY AFFAIRS
PO Box 18300
GREENSBORO, NC 27419-8300

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 15-SEP-10. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.


Receipt for Section 3
S: 882228
Resubmission: Yes No
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: Amendment
Billable: Yes No
Company: 100 SYNGENTA CROP PROTECTION, INC.
Print Letter
Enter More Information
Tracking
Risk Manager: Registration Division, Risk Management Team 7
Product #: 100-1309
Product Name: EMAMECTIN BENZOATE 4.0% TREE INJECTIO
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 14-Sep-2010
OPP Rec'vd Date: 15-Sep-2010
Front End Date: 15-Sep-2010
Risk Manager Send Date: 15-Sep-2010
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Des
Study
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
response to EPA review request for additional chromatograms for pollen analysis
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

Thomas J. Parshley
Senior Regulatory Product Manager
Syngenta Regulatory Affairs
Lawn and Garden Products
(336) 632-7207 (phone)
(336) 632-5688 (fax)
tom.parshley@syngenta.com

482268-00
Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, NC 27419-8300
www.syngenta.com

syngenta

FedEx

September 14, 2010

Document Processing Desk
Office of Pesticide Programs (**7504P**)
U.S. Environmental Protection Agency
2777 South Crystal Drive
Room S-4900, One Potomac Yard
Arlington, VA 22202-4501

Attention: **Mr. Thomas Harris**

SUBJECT: ***EPA REVIEWER REQUEST FOR ADDITIONAL CHROMATOGRAMS FOR POLLEN ANALYSIS TO SUPPORT REQUEST TO EXPAND TREE SPECIES FOR EMAMECTIN BENZOATE 4.0% TREE INJECTION, EPA REG NO. 100-1309***

Dear Mr. Harris:

Enclosed please find the following information in support of the subject request:

- Transmittal Document
- Three copies of the data volume containing the subject information.

The pending amendment action is an ongoing PRIA action and the fee for this action has already been paid. The enclosed additional information was requested by your office in an e-mail dated September 4, 2010, and our response was dated September 8, 2010 (copies enclosed).

Please contact me at (336) 632-7207 if there are any questions concerning this submission or the subject pending registration action.

Sincerely,

Thomas J. Parshley

Thomas J. Parshley
NAFTA Senior Regulatory Product Manager
Syngenta Regulatory Affairs

Enclosed data submission

VOLUME 1 OF 2 OF SUBMISSION (TRANSMITTAL DOCUMENT)

1. Name and Address of Submitter

Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, NC 27419

2. Regulatory Action in Support of which this Package is Submitted

EPA REVIEWER REQUEST FOR ADDITIONAL CHROMATOGRAMS FOR POLLEN ANALYSIS TO SUPPORT REQUEST TO EXPAND TREE SPECIES FOR EMAMECTIN BENZOATE 4.0% TREE INJECTION, EPA REG NO. 100-1309.

3. Transmittal Date

09/14/2010

4. List of Submitted Studies

MRID NUMBER	VOLUME NUMBER	STUDY TITLE	EPA GUIDELINE NUMBER
	1 OF 2	Transmittal Document	N/A
48226801	2 OF 2	Supplemental Information for the Hazard Assessment of Emamectin Benzoate (Tree-Age) Tree Injection to Pollinators (Addendum to EPA MRID 47767401), , (MK244_50179)	Not Applicable

COMPANY OFFICIAL THOMAS J. PARSHLEY (NAME) Thomas J Parshley (SIGNATURE)

COMPANY NAME: SYNGENTA CROP PROTECTION

COMPANY CONTACT: THOMAS J. PARSHLEY (NAME) (336) 632-7207 (PHONE)

Fw: Emamectin Benzoate 4% Tree Injection DP 381025; Amendment to Expand Tree Species, EPA Reg. No. 100-

Thomas Harris to: Pamela Hurley 09/09/2010 11:21 AM

Pam,

Attached below is a .pdf of the chromatograms you requested. They will also submit a paper copy so there will eventually be another MRID to reference (it will also be linked to the original MRID in our database).

ALSO, Syngenta suggested they have their bee risk assessor give you a call to answer any questions. Would that be useful to you?

Cherry Pollen Chromatograms.pdf

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides
----- Forwarded by Thomas Harris/DC/USEPA/US on 09/09/2010 11:19 AM -----

From:	<tom.parshley@syngenta.com>
To:	Thomas Harris/DC/USEPA/US@EPA
Date:	09/09/2010 10:16 AM
Subject:	RE: Emamectin Benzoate 4% Tree Injection DP 381025; Amendment to Expand Tree Species, EPA Reg. No. 100-

Tom: I had an additional thought about the supporting information for the tree injection expansion as we were preparing the data volume this morning for formal submission. Since there have been a few moving parts to this action, I thought it might be a good idea if my bee risk assessor, Jay Overmyer, as a professional courtesy, had a brief conversation with Pam Hurley of EFED to make sure she understands the data, why we did what we did, etc. and to answer any questions she may have regarding the various pieces of information that have been generated over time. Jay won't advocate any position or anything like that, but just be a resource for her in case she has any additional questions on our approach, especially since this is a bit out of the ordinary situation. Would that be acceptable to both you and Pam?

Tom

-----Original Message-----
From: Parshley Tom USGR
Sent: Wednesday, September 08, 2010 3:11 PM
To: 'harris.thomas@epamail.epa.gov'
Subject: RE: Emamectin Benzoate 4% Tree Injection DP 381025; Amendment to Expand Tree Species, EPA Reg. No. 100-

Tom: Attached is an electronic version of the chromatograms for the emamectin benzoate cherry tree residue (pollen) work referenced in the pollinator risk assessment document currently under review by EPA for the subject action. Syngenta will work up a formal addendum to the pollinator risk assessment (EPA MRID NO 47767401) and submit it through the front end screen as a data submission so a new EPA MRID NO can be assigned, which then will be linked to the original assessment document. The last page in the PDF includes a table with the sample ID with the values summarized; these were values which were used in the assessment.

Please let me know if I can provide anything additional.

Best regards,

Tom

-----Original Message-----
From: harris.thomas@epamail.epa.gov [mailto:harris.thomas@epamail.epa.gov]
Sent: Saturday, September 04, 2010 9:31 PM
To: Parshley Tom USGR
Subject: Fw: Emamectin Benzoate 4% Tree Injection DP 381025

Tom,

Could you please check to see if you have the treatment chromatograms for the emamectin pollinator study (see note from reviewer below). If you have them please submit a) a scanned electronic copy emailed to me so I can forward to reviewer to keep review moving, and b) a paper copy formatted for MRID assignment noting in your cover letter that this new material goes with the MRID number we sent you when you submitted the full study paper copy (that way the new material gets tied to the old MRID). Thanks.

note: I'm out of the office at the moment so if you email me with any questions I probably won't get to them until Thur 9/9 when I return to the office.

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides
----- Forwarded by Thomas Harris/DC/USEPA/US on 09/04/2010 09:24 PM -----

From: Pamela Hurley/DC/USEPA/US

To: Thomas Harris/DC/USEPA/US@EPA

Cc: Dana Spatz/DC/USEPA/US@EPA

Date: 08/25/2010 02:12 PM

Subject: Emamectin Benzoate 4% Tree Injection DP 381025

I sent the material that the Registrant sent to us to the HED chemist who is helping me with this action. The Registrant submitted everything except one thing. They sent in the chromatograms of emamectin in pollens for the controls but not for the treated trees. Can you please ask if the Registrant can send those to us? If they have the control chromatograms, they should have the treated. Thanks! When they submit that and I write it up, I need to pass it by the pollinators group.

Pam

This message may contain confidential information. If you are not the designated recipient, please notify the sender immediately, and delete the original and any copies. Any use of the message by you is prohibited.

Memorandum

Date: 8/5/10

To: PM 7, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:
- ☒ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

August 3, 2010

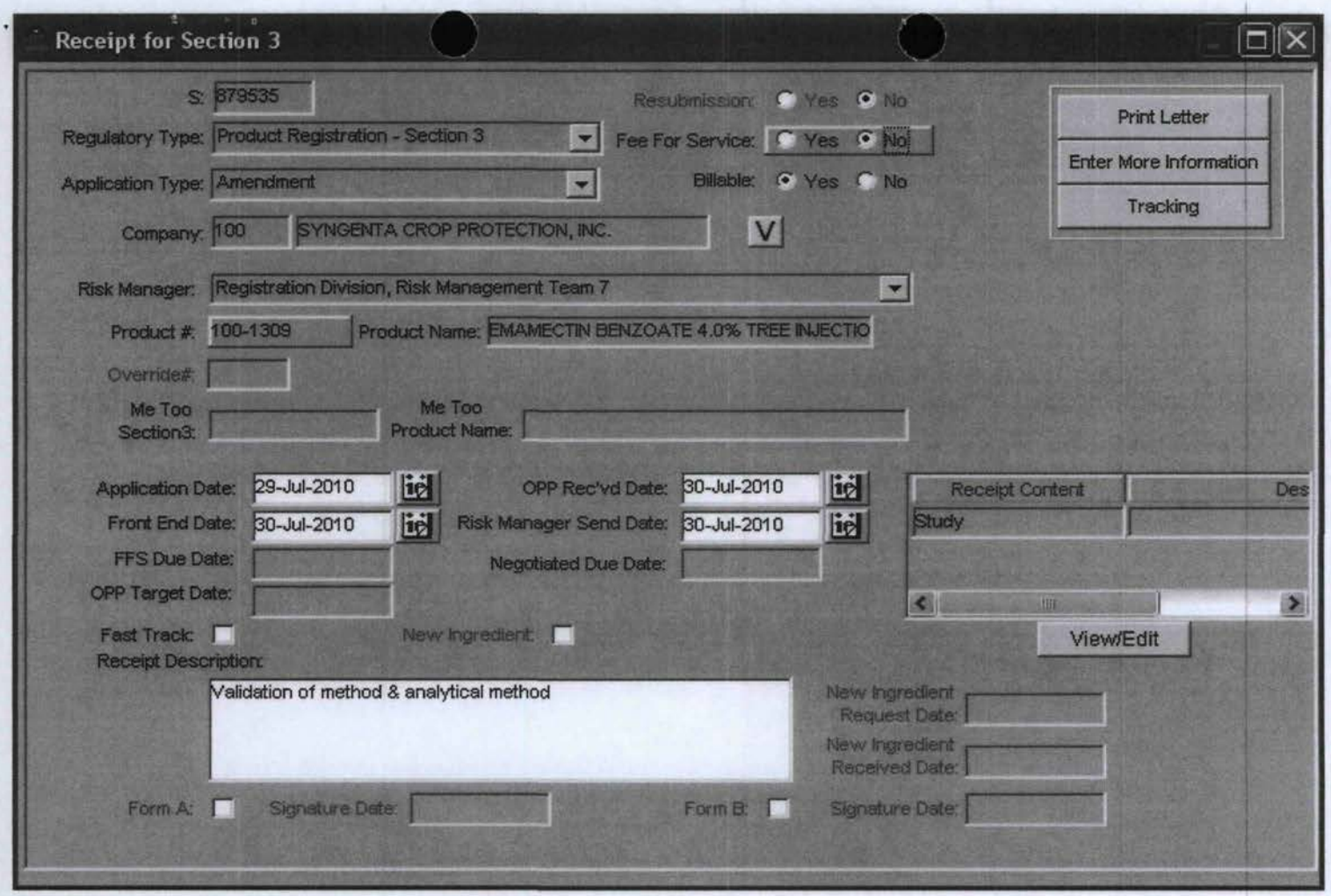
OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SYNGENTA CROP PROTECTION, INC.
ATTN: REGULATORY AFFAIRS
PO Box 18300
GREENSBORO, NC 27419-8300

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 30-JUL-10. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.


Receipt for Section 3
S: 879535
Resubmission: Yes No
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: Amendment
Billable: Yes No
Company: 100 SYNGENTA CROP PROTECTION, INC.
Print Letter
Enter More Information
Tracking
Risk Manager: Registration Division, Risk Management Team 7
Product #: 100-1309
Product Name: EMAMECTIN BENZOATE 4.0% TREE INJECTIO
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 29-Jul-2010
OPP Rec'vd Date: 30-Jul-2010
Front End Date: 30-Jul-2010
Risk Manager Send Date: 30-Jul-2010
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Des
Study
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
Validation of method & analytical method
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

Syngenta Crop P[illegible]tion, Inc. Tel 336 632 6000
P.O. Box 18300
Greensboro, NC 27419-8300
www.syngenta.com

481700-00

syngenta

FEDERAL EXPRESS

July 29, 2010

Document Processing Desk
Office of Pesticide Programs **(7505P)**
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Attention: Thomas Harris

SUBJECT: ***ADDITIONAL INFORMATION TO SUPPORT REQUEST TO EXPAND TREE SPECIES FOR EMAMECTIN BENZOATE 4.0% TREE INJECTION, EPA REG NO. 100-1309***

Dear Mr. Harris:

Enclosed please find the following information in support of the subject request:

- Three copies each of a transmittal document and a two (2) data volumes containing additional information to support expansion of tree species for this product.

The pending amendment action is an ongoing PRIA action and the fee for this action has already been paid. The enclosed additional data was requested by your office in an e-mail dated July 23, 2010 (copy enclosed). The information requested included a description of the analytical method, recovery data, and chromatograms of the emamectin concentration in pollen.

This is the third submission of information to support expansion of tree species for this product, so the enclosed data should be associated with the two previous submissions consisting of cherry residue data and a safety assessment for bees. These documents were assigned EPA MRID Nos. 47767401 (cherry tree residue data) and 47979301 (bee safety assessment).

Please contact me at (336) 632-7207 if there are any questions concerning this submission or the subject pending registration action.

Sincerely,

Thomas J Parshley

Thomas J. Parshley
NAFTA Senior Regulatory Product Manager
Syngenta Regulatory Affairs

Enclosed data submission

VOLUME 1 OF 3 OF SUBMISSION
(TRANSMITTAL DOCUMENT)

1. Name and Address of Submitter

Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, NC 27419

2. Regulatory Action in Support of which this Package is Submitted

Additional Information to Support Request to Expand Tree Species for Emamectin Benzoate 4.0% Tree Injection, EPA Reg. No. 100-1309

3. Transmittal Date

07/29/2010

4. List of Submitted Studies

MRID NUMBER	VOLUME NUMBER	STUDY TITLE	EPA GUIDELINE NUMBER
	1 OF 3	Transmittal Document	N/A
48170001	2 OF 3	Validation of Analytical Method GRM004.04A for the Determination of Emamectin-Benzoate in Tree Parts by LC-MS/MS, (MK244_50157)	860.1340
48170002	3 OF 3	Analytical Method GRM004.04A for the Determination of Emamectin-Benzoate in Tree Parts by LC-MS/MS, GRM004.04A , (MK244_50156)	860.1340

Thomas J Parshley

COMPANY OFFICIAL: Thomas J. Parshley (NAME) _____ (SIGNATURE)

COMPANY NAME: SYNGENTA CROP PROTECTION, INC.

COMPANY CONTACT: Thomas J. Parshley (NAME) (336) 632-7207 (PHONE)

need additional info for emamectin pollinator review

Thomas Harris to: tom.parshley 07/23/2010 03:31 PM

>>> NOTE: This will be the official transmittal of this review and request; a paper copy will not be sent in the mail.

Tom,

I just received the attached memo from EFED regarding the pollinator data we're looking at for emamectin tree injection. Please send in the info requested formatted so it can get assigned an MRID. Please mention in the cover letter that this new MRID is additional info requested which is related to MRID 477674-01 (that way we'll tie the MRIDs together). If you have any questions just give me a call. Thanks.

EFED.pollinator.more info needed.20100722.122806.emamectin.100-1309.DP375084.image.pdf

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

July 22, 2010

PC Code: 122806
DP Barcode: 375084

MEMORANDUM

Subject: Request for Expansion of Tree Species for Emamectin Benzoate Tree Injection Use to Control Arthropod Pests

To: Thomas Harris
Insecticide/Rodenticide Branch
Registration Division

From: Pamela Hurley, Toxicologist
Dana Spatz, Chief
Environmental Risk Branch 3
Environmental Fate and Effects Division
Office of Pesticide Programs

Attached please find the Environmental Fate and Effects Division's (EFED) response to the request for additional tree species to the use of emamectin benzoate as a tree injection insecticide to control arthropod pests.

Background:

The key findings of the original risk assessment for this use (B. Anderson to T. Harris, dated 1/13/09; D351736) included the following points:

"There is no standard methodology currently used by EFED to evaluate potential ecological risks from tree injection of insecticides. However, this screening level risk assessment identified potential risks to terrestrial invertebrates that forage on treated trees. Potential risks to birds, mammals, and terrestrial invertebrates also presumably exceed levels of concern, and potential risks to aquatic invertebrates could not be precluded.

Risk estimates were based on screening-level estimates of exposure. Submission of a study that measures the fate, uptake and translocation (magnitude of residues study) of emamectin benzoate in trees after injection would allow for a refined estimate of exposure and would be of high value to this risk assessment. This type of study requires submission of a formal protocol prior to study initiation and should include an evaluation of the magnitude of residues in edible parts of treated trees, including leaves, nectar, fruit, seeds, and pollen. Without submission of a study to allow for a refined estimation of potential exposures and risks to non-target animals, evaluating the effectiveness of potential mitigation options is not possible. In addition, submission of an acute oral LD_{50} study in bees would be of high value to this assessment.

Label statements that restrict the timing of application of emamectin benzoate and the type of tree that may be treated may be effective in limiting potential risks to non-target organisms. Such label statements may be developed after submission of the magnitude of residues study and would need to be vetted through EFED, RD, and the pollinators team. Without submission of such a study, label statements similar to those recently developed for several neonicotinoid insecticides may be adapted."

EFED Response:

In response to the request for a magnitude of residues study of emamectin benzoate in trees following injection, the Registrant submitted summary data on cherry (*Prunus avium*) pollen residues following injection of the emamectin benzoate formulation, Tree-Age®. In addition, literature articles on pollen selection by honey bees were submitted. The cherry summary data were reviewed by the Health Effects Division (HED) in order to determine whether or not it is sufficient for use in an ecological risk assessment. HED requests the following data from the study so that the residue values may be verified:

- A description of the analytical method
- Recovery data
- Chromatograms of the emamectin concentrations in pollens

Therefore, at this time, EFED had no additional information to assess the potential ecological risk from the proposed use as a tree injection insecticide.

Re: Fw: WITH STUDY: DP# 375084 Emamectin Tree Injection Submission

Leung Cheng to: Pamela Hurley 07/16/2010 10:36 AM
Cc: Thomas Harris, Paula Deschamp

Pam,

Thank you for stopping by earlier this week and let me look through the submission package.

I have the following comments regarding the residue chemistry aspect.

1) A description of the analytical method and the recovery data were not included.
2) We are unable to verify the emamectin concentrations in pollens without the chromatograms.

Lee

Pamela Hurley Hi Lee. I have a label request to expand the tree... 07/12/2010 02:57:39 PM

From: Pamela Hurley/DC/USEPA/US
To: Leung Cheng/DC/USEPA/US@EPA
Cc: Brian Anderson/DC/USEPA/US@EPA
Date: 07/12/2010 02:57 PM
Subject: Re: Fw: WITH STUDY: DP# 375084 Emamectin Tree Injection Submission

Hi Lee. I have a label request to expand the tree species for emamectin benzoate tree injection usage. In the previous EFED risk assessment for tree injection use (Brian this was from you), there was concern for potential risk to birds, mammals and terrestrial invertebrates (especially honey bees) that forage on treated trees. What we asked for was a study that "measures the fate, uptake and translocation (magnitude of residues study) of emamectin benzoate in trees after injection". We had asked for a formal protocol prior to study initiation. The protocol was to include "an evaluation of the magnitude of residues in edible parts of treated trees, including leaves, nectar, fruit,, seeds and pollen." What they sent were some summaries of data on cherry trees and a hazard assessment. It may not be enough for us to use, but I wanted to make sure. Do you want to get together to discuss this? Brian, could you come too since this one is different and it would be a good idea to have several people discussing what to do with this?

Pam

Leung Cheng Hi Pam, I have not looked at the document yet.... 07/12/2010 08:32:17 AM

From: Leung Cheng/DC/USEPA/US
To: Pamela Hurley/DC/USEPA/US@EPA
Date: 07/12/2010 08:32 AM
Subject: Fw: WITH STUDY: DP# 375084 Emamectin Tree Injection Submission

Hi Pam,

I have not looked at the document yet. As Paula said, what are you looking for from HED?

Lee
----- Forwarded by Leung Cheng/DC/USEPA/US on 07/12/2010 08:30 AM -----

From: Paula Deschamp/DC/USEPA/US
To: Leung Cheng/DC/USEPA/US@EPA
Date: 06/24/2010 03:40 PM
Subject: Re: Fw: WITH STUDY: DP# 375084 Emamectin Tree Injection Submission

Thanks very much! It should be fairly easy - you might want to touch base with Pam H. and ask her what she needs.....might save you some time. PD

Leung Cheng Paula, Yes, I will take a look at it after 7/8. Lee 06/24/2010 02:37:53 PM

From: Leung Cheng/DC/USEPA/US

To: Paula Deschamp/DC/USEPA/US@EPA
Date: 06/24/2010 02:37 PM
Subject: Re: Fw: WITH STUDY: DP# 375084 Emamectin Tree Injection Submission

Paula,

Yes, I will take a look at it after 7/8. Lee

Paula Deschamp | Lee, Would you be able to take a look at the resi... | 06/24/2010 10:05:02 AM

From: Paula Deschamp/DC/USEPA/US
To: Leung Cheng/DC/USEPA/US@EPA
Date: 06/24/2010 10:05 AM
Subject: Fw: WITH STUDY: DP# 375084 Emamectin Tree Injection Submission

Lee,

Would you be able to take a look at the residue chemistry study and give Pam Hurley in EFED input on its merits? I know you are working on fluopyram refinements.....would you have time after the 7/8 fluopyram briefing? I don't think we need a bean.....an e:mail response to Pam with cc: to Tom Harris in RD should suffice - provided that's okay with EFED.

----- Forwarded by Paula Deschamp/DC/USEPA/US on 06/24/2010 10:00 AM -----

From: Thomas Harris/DC/USEPA/US
To: Paula Deschamp/DC/USEPA/US@EPA
Date: 06/14/2010 04:21 PM
Subject: WITH STUDY: DP# 375084 Emamectin Tree Injection Submission

Fw: WITH STUDY: DP# 375084 Emamectin Tree Injection Submission

Thomas Harris to Pamela Hurley 06/24/2010 11:37 AM

Pam,

Here's an answer to your request for help from HED on residue questions.

They will take a look at the submission and send you residue comments in an email. Is that sufficient or do you need a formal DP? Just let me know.

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides
----- Forwarded by Thomas Harris/DC/USEPA/US on 06/24/2010 11:35 AM -----

From:	Paula Deschamp/DC/USEPA/US
To:	Thomas Harris/DC/USEPA/US@EPA
Date:	06/24/2010 10:06 AM
Subject:	Re: WITH STUDY: DP# 375084 Emamectin Tree Injection Submission

Tom,
I've asked Leung Cheng to look at the residue data. Unless EFED needs a formal memo, I don't think we need a bean. Lee can provide his evaluation in an e:mail. Let me know if this is okay with EFED.
Thanks, PD

Thomas Harris | I meant to attach the residue study so you could... | 06/14/2010 04:21:53 PM

From:	Thomas Harris/DC/USEPA/US
To:	Paula Deschamp/DC/USEPA/US@EPA
Date:	06/14/2010 04:21 PM
Subject:	WITH STUDY: DP# 375084 Emamectin Tree Injection Submission

I meant to attach the residue study so you could see the info that provided and decide if this would be something you could assist EFED with.

[attachment "47767401.tif" deleted by Paula Deschamp/DC/USEPA/US]

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides
----- Forwarded by Thomas Harris/DC/USEPA/US on 06/14/2010 04:08 PM -----

From:	Thomas Harris/DC/USEPA/US
To:	Paula Deschamp/DC/USEPA/US@EPA
Cc:	John Hebert/DC/USEPA/US@EPA, Meredith Laws/DC/USEPA/US@EPA
Date:	06/14/2010 12:35 PM
Subject:	Fw: DP# 375084 Emamectin Tree Injection Submission

Paula,

Emamectin has one product registered for injection into trees (100-1309), specifically ash trees for emerald ash borer (EAB). Given the importance of this quarantine pest we registered the product but limited it to this single use. Before Syngenta can expand to other ornamental trees we need to analyze how the emamectin partitions in the tree (especially pollen) and then decide if there will be an effect on

pollinators. This will be especially interesting since the label includes a two-year efficacy claim, i.e. the stuff sticks around a while. *[The avermectin tree injection products avoid this issue by saying inject post bloom only . However, we have no long term data we don't really know if avermectin is still in the tree the next year or not..]*

EFED has a DP that includes a residue study (MRID 47767401) and a literature review/pollinator risk analysis. They would like some help with the residue study in terms of how it was done, whether they looked at the right metabolites, etc.
>>>>> Is that something one of your residue chemists could help with? Let me know if you would like a DP (I assume yes).

This is a PRIA action with a due date of 11/5/10. However, unless there is an obvious non-risk to pollinators, I suspect this is just the beginning of a pollinator risk assessment. We'll probably want more studies. Since this is all new, however, the question is what an how to analyze it. Most of this is EFED's issue, they just need help with the residue chemistry.

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides
----- Forwarded by Thomas Harris/DC/USEPA/US on 06/14/2010 12:16 PM -----

From:	Pam[redacted]
To:	Thomas Harris/DC/USEPA/US@EPA, Dana Spatz/DC/USEPA/US@EPA
Cc:	Pamela Hurley/DC/USEPA/US@EPA
Date:	06/14/2010 10:59 AM
Subject:	DP# 375084 Emamectin Tree Injection Submission

My lotus notes isn't working, so I am sending this email from my home account. The previous risk assessment for this use suggested submission of a magnitude of residues study of emamectin benzoate in trees after injection. It also stated that a formal protocol should be submitted prior to the study initiation. Third, it also discussed label statements that may be developed after submission of the magnitude of residues study would need to be vetted through EFED, RD and the pollinators team. From what I can see, a study protocol was not submitted. Instead, some sort of residue study was conducted and presented as part of a hazard assessment (MRID 47767401). I do not know whether or not this study is adequate because I am not a residue chemist. I will need to have an HED chemist involved in this review. I will also need to involve the pollinators team. Can you please make a request to HED to have them involved with this assessment? Thank you.

Pam

Personal privacy information

Treeage - need to bring current advertising/sales up-to-date

Thomas Harris to: tom.parshley 05/11/2010 03:14 PM

Cc: fred.pearson, Meredith Laws, John Hebert

Tom,

Syngenta needs to work with your distribution network to ensure that the sales and advertising information currently being communicated regarding Treeage (100-1309) is up to date. Specifically, you need to make sure that all references to the now cancelled SLN labels are deleted and that current communication states that the product is a Restricted Use Pesticide for use only by certified applicators.

As you recall, Treeage was initially made available for use under a dozen FIFRA 24(c) Special Local Need (SLN) labels which accompanied a generically labeled (but not yet federally registered) bottle of product. EPA issued the Sec 3 registration for Treeage in 7/09 as a Restricted Use Pesticide with an amendment 11/09 to add the 2-year efficacy claim. After our discussion this past winter you cancelled all the SLNs as of 3/10, recalled all the generically labeled/non-registered product, and moved the Sec 3 product into production to have Treeage (as distributed by Arborjet) available in the market ASAP.

It was just brought to our attention that the May 2010 catalog for A. M. Leonard (241 Fox Drive, PO Box 816, Piqua, OH 45356. (800) 543-8955. www.amleo.com) offers Treeage for sale in their pesticide section. It states that the product is registered for use in certain states (i.e. it's referring to the SLNs), is effective for 2+ years, and states that the product is "not intended for homeowners". Obviously, there is a lead time required to print catalogs so I am not surprised to see the SLN product still referenced in print. However, the A. M. Leonard website still lists the SLN product as available as of today (5/11/10) even though the RUP Sec 3 was registered on 7/11/09 and the SLNs were cancelled on 3/12/10. The SLN product needs to be deleted from their lists of available products. It is unclear to me whether A. M. Leonard has the ability to authenticate and track sales of RUP products.

In addition, I just checked the Arborjet website. Arborjet lists the correct federally registered RUP label and has a fairly recent (4/26/10) list of states which have registered the product for use in their state. All is well here except one note on the main Treeage page (http://www.arborjet.com/products/tree-age.htm) which states "Treeage is not intended for homeowner use" and which leads to URL (http://www.arborjet.com/products/tree-age-disclaimer.pdf) where it states the following:

"Important
Our most recent product addition," TREE-äge", is receiving very positive press coverage and significant interest. As with any new product, it is critical that TREE-äge be properly applied and receive the highest degree of stewardship.
Additionally, tree injection and the control of EAB with TREE-äge are best performed by the Arborist or the Lawn and Landscape professional. As such, Tree-äge should only applied by industry professionals capable of assuring proper application. Homeowners can see the "contact us" section of this website to find an applicator in their area."

The Arborjet homeowner link and statement need to be updated to definitively state that Treeage is a RUP and can only be sold to and applied by a state certified applicator. "Not intended", "best performed", etc are misleading.

As good and responsible stewards of your products I appreciate your prompt attention to correcting these issues.

Tom Harris
EPA/OPPTS/OPP/RD/IRB
voice: (703) 308-9423
fax: (703) 308-0029
harris.thomas@epa.gov
visit http://www.epa.gov/pesticides

PROVEN & EFFECTIVE CONTROL OF EMERALD ASH BORER

Injection Equipment: Simply drill, plug, and inject. Uses a sealed injection system that delivers treatments quickly, with no risk of cambial injury.. Treatment takes about 40-50 seconds per caliper inch, or 7-8 minute per tree when treating multiple trees. Choose the system sized for your needs. The Quik-Jet manually injects one tree at a time. The Tree IV kits allow you to inject multiple trees efficiently, with no waiting between trees.

QUIK-Jet Pro
Simply fill the 1 liter injection bottle and go. You adjust dose from 1-5 milliliters as you inject.. Includes: injection device, tubing, bottle, (2) needles, Clean-Jet solution sample, tool kit, safety glasses, funnel, graduated cylinder, monster hook, bottle clip, waterproof storage bag, and complete instructions.
702250 Ship wt. 6 lb..... **$345.99**

Tree IV Micro Infusion 2-pack – A perfect starter kit. Includes everything you need to treat two trees simultaneously: bucket, (2) IV bottles, (8) valve assemblies, (2) IV 4-line manifolds, (4) tree IV stands, (2) needle clean out tools, pressure pump, IV tool kit, drill bit, arborplug setter, graduated cylinder, liter of Clean-Jet solution, funnel, and complete instructions.
700010 Ship wt. 13 lb..... **$604.99**

Injectable Solutions

TREE-Age Systemic Insecticide
Our newest and most effective insect control, currently registered for use against EMERALD ASH BORER in; Illinois, Indiana, Ohio, Michigan, Minnesota, W. Virginia. Independent university research has proven up to 2+ years of extremely effective control against EAB from a single treatment. You CAN save your customers Ash Trees! Not intended for homeowners. Treat 18-10" trees / liter

404000 1 liter Ship wt. 3 lb..... **$541.49**
404005 1 liter x 8 case Ship wt. 22 lb..... **$4023.99**

IMA-Jet Systemic Insecticide
Very effective control against emerald ash borer, and manages many other insect pests of forests, trees, ornamentals, and interior plantscapes, including: Adelgid, aphids, lace bugs, leafhoppers, leaf miners, bronze birch borer and more. Up to 3 yrs. control against HWA.

402003 1 liter Ship wt. 3 lb..... **$308.49**
402004 1 liter x 8 case Ship wt. 22 lb..... **$2266.99**

NEW Arborplugs
Arborplug creates the perfect injection interface that limits wounding, speeds healing while inhibiting infection and insect entry. 3/8" size is perfect for conifers and most medium to large trees.

0700155 100 plugs Ship wt. 1 lb..... **$54.99**

DETERRENTS FOR GEESE & OTHER INVADERS

Lifelike Menacing Coyote
Get rid of annoying, and often destructive Canada geese, ducks, rabbits, skunks and other pests with this safe and humane deterrent. Three dimensional, for full 360° coverage: much better than a flat silhouette. Life sized flexible weatherproof EVA resin coyote measures 37". Unfolds and sets up in seconds. Assumes a realistic shape that changes positions in the breeze. Includes: coyote, sturdy metal stake, and a furry tail. 37"L x 8"W x 16"H.

COY3..... **$61.99**
Ship wt. 4 lb

3-D Predator Looks Ready to Pounce, Even from the Air!

Floating Gator Head
This life-sized alligator head floats on your waterway to scare geese, ducks, fish-eating birds and small animals away. Moves and bounces with the water, plus, mirror-backed eyes flash in the sun for even more realism. Three dimensional, 25"L x 11"W x 7"H. Depending on your layout, one gator is recommended per acre of water. Made from flexible weatherproof EVA resin. UV treated for long life. Unfolds and sets up in seconds.

GTG Ship wt. 4 lb..... **$61.99**

Attach Your Spray Can to an Extension Pole – Trigger almost any aerosol spray or powder duster from the safety of the ground. Excellent for wasp and hornet control, dusting for wood-boring bees, applying pruning sealer, testing smoke detectors, painting, or cleaning windows. Use spray head with any standard-threaded extension pole (not included).

Ship wt. 1 lb
GSP0205..... **$29.99**

Bird Spikes™ Roost Inhibitor
For a humane solution to an aggravating problem, apply these sharp spikes wherever birds land or roost: ledges, sills, cornices, signs, beams, etc. Kit includes 10 feet of clear polycarbonate needle stripping and permanent adhesive. Spikes can also be tied or screwed onto surfaces. 10 sections, each measuring 12"L x 2.25"W x 4.5"H. One row of spikes is recommended for every 2" of width in the protected area.

SP10NR Ship wt. 3 lb..... **$19.99**

Milky Spore
Naturally occu
Japanese Bee
lawn grubs. A
hatch and des
Insects are in
feeding. Once
decay, releasi
into the soil.
flower garden
Once establis
be seen for u
2,500 square

Ship wt. 1 lb
MS10 .....

Conserve®
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in one to thre
odor. 1 quart.

CS32 Ship

Yellow Tang
These bright
sticky adhesi
for monitorin
Each 3" x 10"
two-sided ap
flies, aphids,
Lasts all seas
with twist ties
grid simplifies
3 cards per p

YT310.....

NEW Yellow
Adhesive card
toxic trap use
trapping pest
used for aphi
fungus gnats,
been found to
thrips. Heavy
with peel-off

Ship wt. .5 lb.
PT58-4Y.....
PT58-3B.....

FERTILIZERS, TREATMENTS & REPELLENTS

www.amleo.com

1–80

EST. 1885

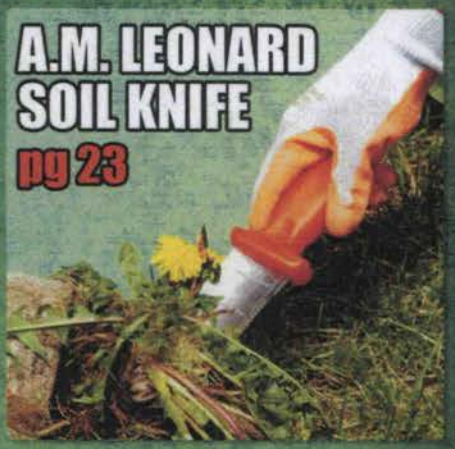
May 2010

A.M. LEONARD

HORTICULTURAL TOOL & SUPPLY COMPANY

CONTROLLED RELEASE FERTILIZER pg 3

A.M. LEONARD'S ARBOR RAIN pg 211



A.M. LEONARD SOIL KNIFE pg 23

A.M. LEONARD FULL STRAP SPADE pg 210

INTRO PRICE $89.99

NEW

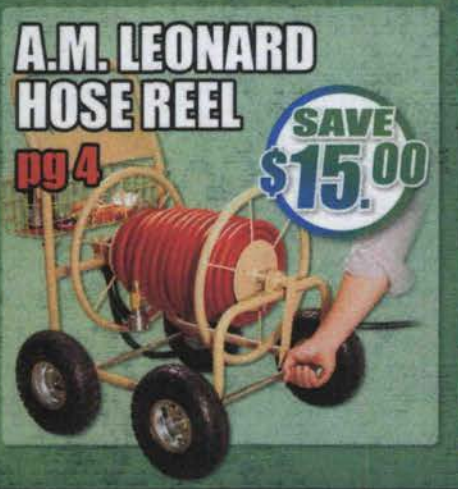
GROUND SHIPPING - JUST $4.99 FOR 12 MONTHS

NO UP-FRONT CHARGES.

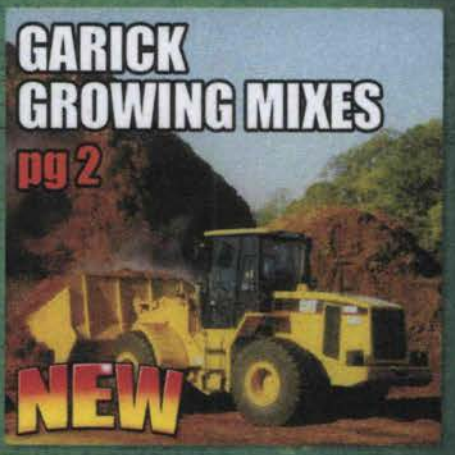
SAFETY CANS pg 208

TAGGING TAPE pg 209

SINCE 1885 125 ANNIVERSARY 2010



A.M. LEONARD HOSE REEL pg 4



GARICK GROWING MIXES pg 2

Phone 800-543-8955 Web amleo.com

21-Day Screen of Amendment
(Completed by Contractor)

21-day Expires on 3-5-10

Document Part Of: 100-1309
MRID, If Any: 479793

Content Screen: Recommended to
Pass/Fail

86-5 Review: Passed/Failed/NA

Document returned to:

LINDA ARRINGTON

PM-7

Completion of 21-Day Content Screen

PM- 7

EPA Reg. #(File Symbol) 100-1305

Decision # D 427963

Data package delivered to you on 8/19/10.
(date)

Jacket/Mini-jacket will be transferred to you today.
(Pick up from Document Center)

Thank you,

Registration Division's 21–Day Content Team

100-1305

Memorandum

Date: 02 / 18 / 10

To: PM 7, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:
- ☑ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

February 18, 2010

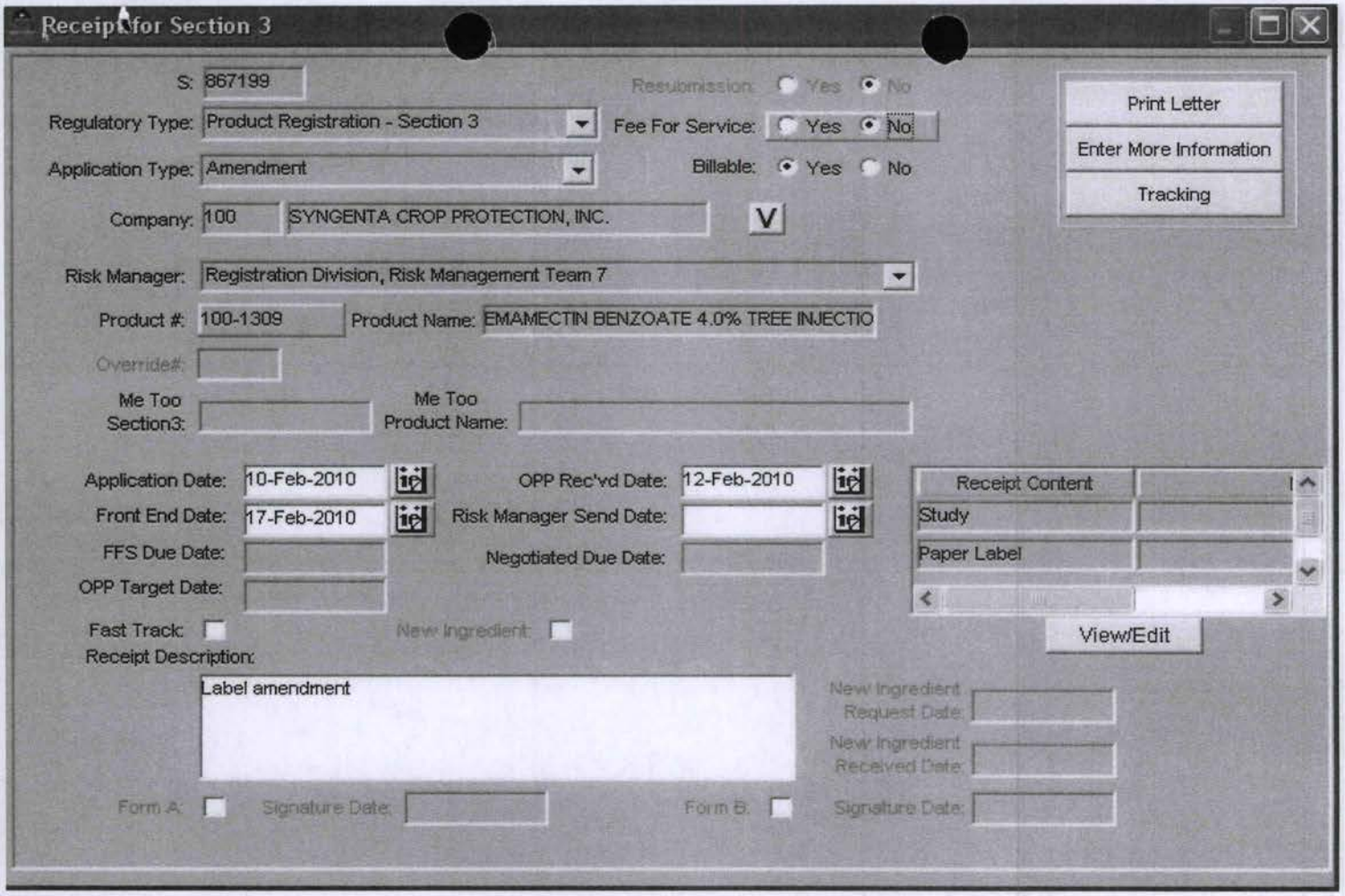
OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SYNGENTA CROP PROTECTION, INC.
PO Box 18300
GREENSBORO, NC 27419-8300

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 12-FEB-10. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.


Receipt for Section 3
S: 867199
Resubmission: Yes No
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: Amendment
Billable: Yes No
Print Letter
Enter More Information
Tracking
Company: 100 SYNGENTA CROP PROTECTION, INC.
V
Risk Manager: Registration Division, Risk Management Team 7
Product #: 100-1309
Product Name: EMAMECTIN BENZOATE 4.0% TREE INJECTIO
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 10-Feb-2010
OPP Rec'vd Date: 12-Feb-2010
Front End Date: 17-Feb-2010
Risk Manager Send Date:
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Study
Paper Label
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
Label amendment
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

syngenta

FEDERAL EXPRESS

February 10, 2010

Document Processing Desk **(AMEND)**
Office of Pesticide Programs **(7504P)**
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: **Mr. Thomas Harris**

SUBJECT: ***SUBMISSION OF REQUEST TO EXPAND TREE SPECIES FOR EMAMECTIN BENZOATE 4.0% TREE INJECTION (TREEÄGE™) EPA REG NO. 100-1309***

Dear Mr. Harris:

Enclosed please find the following information in support of the subject request:

- Receipt for payment of PRIA II fee
- Application for Pesticide Amendment, EPA Form 8570-1
- Certification with Respect to Citation of Data, EPA Form 8570-34
- Data Matrices for emamectin benzoate technical active ingredient and the end use product, EPA Form 8570-35
- Transmittal document
- One (1) data volume containing information to support expansion of tree species for this product
- Certification with Respect to Label Integrity form & a compact disk (CD) with pdf of revised draft product labeling
- Five copies of revised draft product labeling, one (1) with revisions marked

Syngenta is pursuing, through this amendment, approval for addition of more tree species and associated insect pests for this product. Recall that during the initial registration filing and science review process, EPA raised an issue concerning potential risk to pollinators, specifically honey bees. In order to address this issue, Syngenta filed a cherry tree study where pollen samples were analyzed to determine potential residue levels of emamectin benzoate (the active ingredient in Emamectin Benzoate 4.0% Tree Injection. Based on the results of this study, it was determined that concentrations of emamectin benzoate in pollen from injected trees would be below the level of concern. These data were assigned EPA MRID NO. 47767401.

Syngenta Crop[redacted]ection, Inc. Tel 336 632 6000
P.O. Box 18300[redacted]
Greensboro, NC 27419-8300
www.syngenta.com

syngenta

However, EPA was unable to consider these data prior to a registration decision for this product. Consequently, the product use was limited to ash trees for the initial registration.

Since the initial registration was granted, Syngenta has been working to develop further information to address the pollinator issue. The enclosed document, along with the cherry tree pollen residue data and assessment, are being provided to support the proposed expansion of tree species, as noted in the attached draft label. It is our belief that the two studies should provide EPA with evidence that pollinators will not be exposed to emamectin benzoate at concentrations that could harm significant numbers of individuals or cause population-level effects.

Fees for Services

Syngenta believes this is a PRIA R350 action with an 8-month processing timeline and with an associated fee of $11,424 and has prepaid this amount. Please contact me at (336) 632-7207, if there are any questions concerning this submission or the pending registration action for Emamectin Benzoate 4.0% Tree Injection. Please email fee confirmation to pat.eay@syngenta.com.

Sincerely,

Thomas J Parshley

Thomas J. Parshley
NAFTA Senior Regulatory Product Manager
Syngenta Regulatory Affairs

Enclosed data submission

VOLUME 1 OF 2 OF SUBMISSION (TRANSMITTAL DOCUMENT)

1. Name and Address of Submitter

Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, NC 27419

2. Regulatory Action in Support of which this Package is Submitted

Submission of Request to Expand Tree Species for Emamectin Benzoate 4.0% Tree Injection (Treeage), EPA Reg. No. 100-1309.

3. Transmittal Date

02/10/2010

4. List of Submitted Studies

MRID NUMBER	VOLUME NUMBER	STUDY TITLE	EPA GUIDELINE NUMBER
	1 OF 2	Transmittal Document	N/A
47979301	2 OF 2	Use of Emamectin Benzoate (Tree-Age®) Tree Injection in Conifers and Potential Risk to Pollinators, TK0023601, (MK244_50111)	N/A

COMPANY OFFICIAL THOMAS J. PARSHLEY (NAME) Thomas J Parshley (SIGNATURE)

COMPANY NAME: SYNGENTA CROP PROTECTION

COMPANY CONTACT: THOMAS J. PARSHLEY (NAME) (336) 632-7207 (PHONE)

Fee for Service

pem {867199d~

This package includes the following

- ○ New Registration
- ◉ Amendment

□ Studies? □ Fee Waiver?

□ volpay % Reduction: ___

for Division

- ○ AD
- ○ BPPD
- ◉ RD

Risk Mgr. 7

Receipt No. S-	867199
EPA File Symbol/Reg. No.	100-1309
Pin-Punch Date:	2/12/2010

□ This item is NOT subject to FFS action.

Action Code:

Requested: R350

Granted: R350

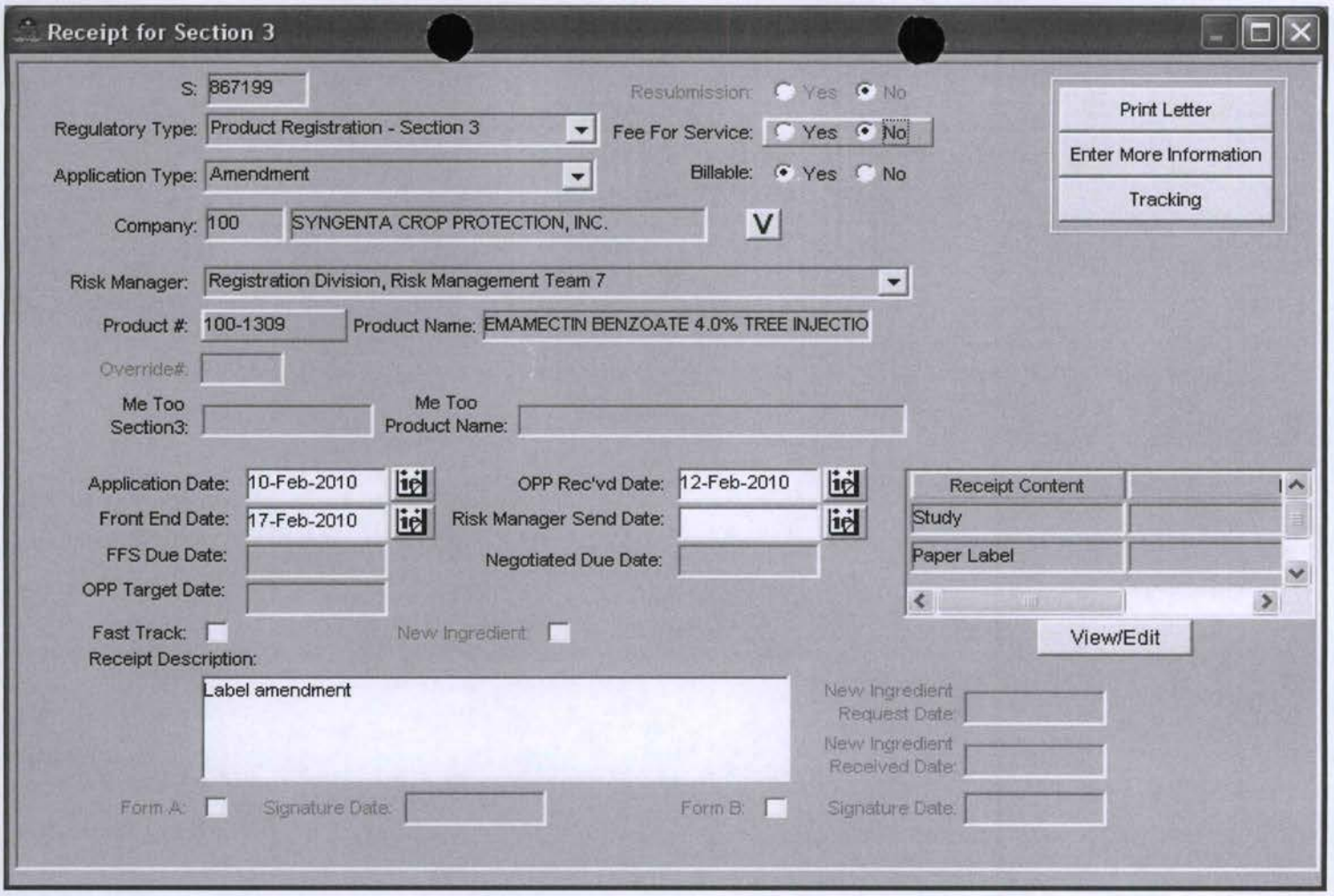
Amount Due: $ 11,424.00

Parent/Child Decisions:

▣ Inert Cleared for Intended Use ▣ Uncleared Inert in Product

Reviewer: [signature] Date: 2/18/10

Remarks: Needs EFED review re: pollinator risk


Receipt for Section 3
S: 867199
Resubmission: Yes No
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: Amendment
Billable: Yes No
Company: 100 SYNGENTA CROP PROTECTION, INC.
V
Print Letter
Enter More Information
Tracking
Risk Manager: Registration Division, Risk Management Team 7
Product #: 100-1309
Product Name: EMAMECTIN BENZOATE 4.0% TREE INJECTIO
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 10-Feb-2010
OPP Rec'vd Date: 12-Feb-2010
Front End Date: 17-Feb-2010
Risk Manager Send Date:
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Study
Paper Label
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
Label amendment
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

February 18, 2010

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-427963
EPA File Symbol or Registration Number: 100-1309
Product Name: EMAMECTIN BENZOATE 4.0% TREE INJECTION
EPA Receipt Date: 12-Feb-2010
EPA Company Number: 100
Company Name: SYNGENTA CROP PROTECTION, INC.

BUNNIE KONAT
SYNGENTA CROP PROTECTION, INC.
ATTN: REGULATORY AFFAIRS
PO Box 18300
GREENSBORO, NC 27419-8300

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R350

NON-FAST TRACK (CHANGES TO REI;PPE;PHI;RATE AND NUMBER OF APPLICATIONS;ADD AERIAL APPLICATION;MODIFY GW/SW ADVISORY STATEMENT;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 305-6249.

Sincerely,
Teresa Downs
Front End Processing Staff
Information Technology & Resources Management Division

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

3/23/09

21 Day Screen Start Date: 2-12-10

Experts In-Processing Signature: MF HARRINGTON Date 2-18-10 Fee Paid: Yes ✓

Division management contacted on issues No_____ Yes _____ Date _____

EPA Reg. Number: 100-1309	EPA Receipt Date: 2-12-10

	Items for Review			Yes	No	N/A*
1	**Application Form** (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	**Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)					X
	a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)	**yes**	**no**			
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	**yes**	**no**			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	**Formulator's Exemption Statement** (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
5	**Data Matrix** (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
		yes	**no**			
	a) Selective Method (Fee category experts use)	X				
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	**5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to** http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels **)**			X		

7	**Is the data package consistent with PR Notice 86-5** (link to PRN 86-5)	X		
8	**Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)**			X
9	**If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)**			X
10	**Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.**			
	a) List study (or studies) not included with application			

Comments:

KC 0 Study associated w/ jacket (MRID 479793) has passed 86-5 review.

Pass MRID 479793

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to http://www.epa.gov/opprd001/inerts/lists.html] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to http://www.epa.gov/opprd001/inerts/tips.pdf] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

syngenta

FEDERAL EXPRESS

February 10, 2010

Document Processing Desk **(AMEND)**
Office of Pesticide Programs **(7504P)**
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Attention: **Mr. Thomas Harris**

SUBJECT: ***SUBMISSION OF REQUEST TO EXPAND TREE SPECIES FOR EMAMECTIN BENZOATE 4.0% TREE INJECTION (TREEÄGE™) EPA REG NO. 100-1309***

Dear Mr. Harris:

Enclosed please find the following information in support of the subject request:

- Receipt for payment of PRIA II fee
- Application for Pesticide Amendment, EPA Form 8570-1
- Certification with Respect to Citation of Data, EPA Form 8570-34
- Data Matrices for emamectin benzoate technical active ingredient and the end use product, EPA Form 8570-35
- Transmittal document
- One (1) data volume containing information to support expansion of tree species for this product
- Certification with Respect to Label Integrity form & a compact disk (CD) with pdf of revised draft product labeling
- Five copies of revised draft product labeling, one (1) with revisions marked

Syngenta is pursuing, through this amendment, approval for addition of more tree species and associated insect pests for this product. Recall that during the initial registration filing and science review process, EPA raised an issue concerning potential risk to pollinators, specifically honey bees. In order to address this issue, Syngenta filed a cherry tree study where pollen samples were analyzed to determine potential residue levels of emamectin benzoate (the active ingredient in Emamectin Benzoate 4.0% Tree Injection. Based on the results of this study, it was determined that concentrations of emamectin benzoate in pollen from injected trees would be below the level of concern. These data were assigned EPA MRID NO. 47767401.

Syngenta Crop Pr[redacted]on, Inc. Tel 336 632 6000
P.O. Box 18300
Greensboro, NC 27419-8300
www.syngenta.com

syngenta

However, EPA was unable to consider these data prior to a registration decision for this product. Consequently, the product use was limited to ash trees for the initial registration.

Since the initial registration was granted, Syngenta has been working to develop further information to address the pollinator issue. The enclosed document, along with the cherry tree pollen residue data and assessment, are being provided to support the proposed expansion of tree species, as noted in the attached draft label. It is our belief that the two studies should provide EPA with evidence that pollinators will not be exposed to emamectin benzoate at concentrations that could harm significant numbers of individuals or cause population-level effects.

Fees for Services

Syngenta believes this is a PRIA R350 action with an 8-month processing timeline and with an associated fee of $11,424 and has prepaid this amount. Please contact me at (336) 632-7207, if there are any questions concerning this submission or the pending registration action for Emamectin Benzoate 4.0% Tree Injection. Please email fee confirmation to pat.eay@syngenta.com.

Sincerely,

Thomas J Parshley

Thomas J. Parshley
NAFTA Senior Regulatory Product Manager
Syngenta Regulatory Affairs

Enclosed data submission

Please read instructions on reverse before completing form.

United States Environmental Protection Agency Washington, DC 20460	[ ] Registration [X] Amendment [ ] Other	OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
100-1309	Thomas Harris	[X] None [ ] Restricted
4. Company/Product (Name)	PM# 4B	
Emamectin Benzoate 4.0% Tree Injection		
5. Name and Address of Applicant *(Include ZIP Code)*	6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:	
Syngenta Crop Protection, Inc. P. O. Box 18300 Greensboro, NC 27419	EPA Reg. No. _____	
[ ] *Check if this is a new address*	Product Name _____	

Section - II

[X] Amendment - Explain below.

[ ] Resubmission in response to Agency letter dated _____

[ ] Notification - Explain below.

[ ] Final printed labels in response to Agency letter dated _____

[ ] "Me Too" Application.

[ ] Other - Explain below. New Product-nonfood use

Explanation: Use additional page(s) if necessary. (For Section I and Section II.).

Amendment to expand tree species beyond ash trees. This is a PRIA R-350 action with a fee of $11,424 which has been prepaid.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [x] No	[ ] Yes [x] No	[ ] Yes [x] No	[ ] Metal [x] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) Plastic tube
***Certification must**	If "Yes" Unit Packaging wgt. / No. per Container	If "Yes" Unit Packaging wgt. / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[x] Label [ ] Container	1 pint to 55 gallons	[x] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product: [ ] Lithograph [x] Paper glued for tubes [ ] Stenciled [ ] Outer box is preprinted _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Thomas J. Parshley	Senior Reg. Product Manager	336-632-7207

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
Thomas J Parshley	Senior Regulatory Product Manager
4. Typed Name	5. Date
Thomas J. Parshley	February 10, 2010

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.

Eay Pat USGR

From: paygovadmin@mail.doc.twai.gov
Sent: Tuesday, February 09, 2010 4:27 PM
To: Eay Pat USGR
Subject: Pay.Gov Payment Confirmation

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

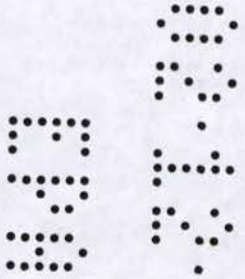
Your transaction has been successfully completed.

Transaction Summary

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 250C1A9J
Agency Tracking ID: 74100812084

Account Holder Name: Janis McFarland
Transaction Type: Sale
Transaction Amount: $11,424.00
Billing Address: P.O. Box 18300
City: Greensboro
State/Province: NC
Zip/Postal Code: 27419
Country: USA
Card Type: Visa
Card Number: **********6187
Transaction Date: Feb 9, 2010 4:26:43 PM

Decision Number:
Registration Number: 100-1309
Company Name: Syngenta Crop Protection
Company Number: 100
Action Code: R350



Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M STREET, S.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27410	100-1309
Active Ingredient(s) and/or representative test compound(s)	Date
Emamectin Benzoate	February 10, 2010
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)	Product Name
Tree Injection for Trees	Emamectin Benzoate 4.0% Tree Injection

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-in Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
Thomas J Parshley	February 10. 2010	Thomas J. Parshley, Senior Regulatory Product Manager

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number	EPA Registration Number/File Symbol
Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27410	100-902
Active Ingredient(s) and/or representative test compound(s)	Date
Emamectin Benzoate	February 10, 2010
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)	Product Name
Tree Injection for Trees	Emamectin Benzoate Technical

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

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I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

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Signature	Date	Typed or Printed Name and Title
Thomas J Parshley	February 10. 2010	Thomas J. Parshley, Senior Regulatory Product Manager

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Certification with Respect to Label Integrity

Version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL		
EPA Registration #	Date Submitted to EPA	Electronic file name
100-1309	February 10, 2010	000100-01309.20100210.pdf

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

Signature

February 10, 2010

Date

Thomas J Parshley

Name (typed)

Sr. Regulatory Product Manager

Title

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street
WASHINGTON, D.C. 20460

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DATA MATRIX

Date: 2/10/2010	Reg. No: 100-1309	Page 1 of 16
Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: Emamectin Benzoate 4.0% Tree Injection	

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
Cite-All	Cite-All	Cite-All (AHE	AGRICULTURAL HAN	PER	
Cite-All	Cite-All	Cite-All (ART	AGRICULTURAL REE	PER	
Cite-All	Cite-All	Cite-All (FES	FIFRA ENDANGERED	PER	
Cite-All	Cite-All	Cite-All (ORE	OUTDOOR RESIDENT	PER	
Cite-All	Cite-All	Cite-All (REJ	RESIDENTIAL EXPOS	PER	
Cite-All	Cite-All	Cite-All (SDT	SPRAY DRIFT TF	PER	
830.1550	Product identity and compostition	47309301	SYNGENTA	OWN	
830.1600	Description of materials used to produce the product	47309301	SYNGENTA	OWN	
830.1620	Description of production process	47309301	SYNGENTA	OWN	
830.1650	Description of Formulation process	47309301	SYNGENTA	OWN	
830.1670	Discussion of formation of impurities	47309301	SYNGENTA	OWN	
830.1750	Certified limits	47309301	SYNGENTA	OWN	

Thomas J Parshley

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 2/10/2010

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DATA MATRIX

Date: 2/10/2010	Reg. No: 100-1309	Page 2 of 16
Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: Emamectin Benzoate 4.0% Tree Injection	

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
830.1800	Enforcement analytical method	47309301	SYNGENTA	OWN	
830.6302	Color	47309302	SYNGENTA	OWN	
830.6303	Physical state	47309302	SYNGENTA	OWN	
830.6304	Odor	47309302	SYNGENTA	OWN	
830.6314	Oxidation/reduction: chemical incompatibility	47309302	SYNGENTA	OWN	
830.6315	Flammability	47309302	SYNGENTA	OWN	
830.6316	Explodability	47309302	SYNGENTA	OWN	
830.6317	Storage Stability	47309302	SYNGENTA	OWN	
830.6319	Miscibility	47309302	SYNGENTA	OWN	
830.6320	Corrosion characteristics	47309302	SYNGENTA	OWN	
830.7000	pH	47309302	SYNGENTA	OWN	
830.7100	Viscosity	47309302	SYNGENTA	OWN	

Thomas J Parshley

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DATA MATRIX

Date: 2/10/2010	Reg. No: 100-1309	Page 3 of 16
Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: Emamectin Benzoate 4.0% Tree Injection	

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
830.7300	Density/relative density/bulk density	47309302	SYNGENTA	OWN	
850 Series	Ecological Effects	47767401	SYNGENTA	OWN	
870.1100	Acute oral toxicity	47309303	SYNGENTA	OWN	
870.1200	Acute dermal toxicity	47309304	SYNGENTA	OWN	
870.1300	Acute inhalation toxicity	47309305	SYNGENTA	OWN	
870.2400	Acute eye irritation	47309306	SYNGENTA	OWN	
870.2500	Acute dermal irritation	47309307	SYNGENTA	OWN	
870.2600	Skin sensitization	47309308	SYNGENTA	OWN	
870.3100	90-Day oral toxicity	42743620	MERCK & CO., INC.	OWN	
870.3100	90-Day oral toxicity	42743621	MERCK & CO., INC.	OWN	
870.3100	90-Day oral toxicity	42743622	MERCK & CO., INC.	OWN	
870.3100	90-Day oral toxicity	42743623	MERCK & CO., INC.	OWN	

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Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

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DATA MATRIX

Date: 2/10/2010	Reg. No: 100-1309	Page 4 of 16
Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: Emamectin Benzoate 4.0% Tree Injection	

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
870.3100	90-Day oral toxicity	42794201	MERCK & CO., INC.	OWN	
870.3100	90-Day oral toxicity	43868103	MERCK & CO., INC.	OWN	
870.3150	Subchronic nonrodent oral toxicity - 90-day	42743620	MERCK & CO., INC.	OWN	
870.3150	Subchronic nonrodent oral toxicity - 90-day	42743621	MERCK & CO., INC.	OWN	
870.3150	Subchronic nonrodent oral toxicity - 90-day	42743622	MERCK & CO., INC.	OWN	
870.3150	Subchronic nonrodent oral toxicity - 90-day	42743623	MERCK & CO., INC.	OWN	
870.3150	Subchronic nonrodent oral toxicity - 90-day	42794201	MERCK & CO., INC.	OWN	
870.3150	Subchronic nonrodent oral toxicity - 90-day	43868103	MERCK & CO., INC.	OWN	
870.3200	Repeated dose dermal toxicity - 21/28 day	42743625	MERCK & CO., INC.	OWN	
870.3200	Repeated dose dermal toxicity - 21/28 day	44007902	MERCK & CO., INC.	OWN	
870.3700	Prenatal developmental toxicity study	42743631	MERCK & CO., INC.	OWN	
870.3700	Prenatal developmental toxicity study	42743632	MERCK & CO., INC.	OWN	

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DATA MATRIX

Date: 2/10/2010	Reg. No: 100-1309	Page 5 of 16
Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: Emamectin Benzoate 4.0% Tree Injection	

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
870.3700	Prenatal developmental toxicity study	42743634	MERCK & CO., INC.	OWN	
870.3700	Prenatal developmental toxicity study	42743635	MERCK & CO., INC.	OWN	
870.3700	Prenatal developmental toxicity study	42743636	MERCK & CO., INC.	OWN	
870.3800	Reproduction and fertility effects	42743633	MERCK & CO., INC.	OWN	
870.3800	Reproduction and fertility effects	42851511	MERCK & CO., INC.	OWN	
870.4100	Chronic toxicity	42743624	MERCK & CO., INC.	OWN	
870.4100	Chronic toxicity	42851510	MERCK & CO., INC.	OWN	
870.4100	Chronic toxicity	42868902	MERCK & CO., INC.	OWN	
870.4100	Chronic toxicity	43868104	MERCK & CO., INC.	OWN	
870.4200	Carcinogenicity	43868104	MERCK & CO., INC.	OWN	
870.4200	Carcinogenicity	43868105	MERCK & CO., INC.	OWN	
870.5000	Genetic Toxicity tests	42743637	MERCK & CO., INC.	OWN	

Thomas J Parshley

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DATA MATRIX

Date: 2/10/2010	Reg. No: 100-1309	Page 6 of 16
Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: Emamectin Benzoate 4.0% Tree Injection	

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
870.5000	Genetic Toxicity tests	42743638	MERCK & CO., INC.	OWN	
870.5000	Genetic Toxicity tests	42743639	MERCK & CO., INC.	OWN	
870.5000	Genetic Toxicity tests	42851512	MERCK & CO., INC.	OWN	
870.5000	Genetic Toxicity tests	42851513	MERCK & CO., INC.	OWN	
870.5000	Genetic Toxicity tests	42851514	MERCK & CO., INC.	OWN	
870.5000	Genetic Toxicity tests	42851515	MERCK & CO., INC.	OWN	
870.5000	Genetic Toxicity tests	42851516	MERCK & CO., INC.	OWN	
870.5000	Genetic Toxicity tests	42851517	MERCK & CO., INC.	OWN	
870.5100	Bacterial reverse mutation test	47002111	SYNGENTA	OWN	
870.6100	Acute and 28-day delayed neurotoxicity of organopho	42743611	MERCK & CO., INC.	OWN	
870.6100	Acute and 28-day delayed neurotoxicity of organopho	42743614	MERCK & CO., INC.	OWN	
870.6100	Acute and 28-day delayed neurotoxicity of organopho	42743626	MERCK & CO., INC.	OWN	

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DATA MATRIX

Date: 2/10/2010	Reg. No: 100-1309	Page 7 of 16
Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: Emamectin Benzoate 4.0% Tree Injection	

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
870.6100	Acute and 28-day delayed neurotoxicity of organopho	42743627	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42743618	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42743619	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42743624	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42743628	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42743629	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42743630	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42851503	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42851504	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42851505	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42851506	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42851507	MERCK & CO., INC.	OWN	

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DATA MATRIX

Date: 2/10/2010	Reg. No: 100-1309	Page 8 of 16
Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: Emamectin Benzoate 4.0% Tree Injection	

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
870.6200	Neurotoxicity screening battery	42851508	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42851509	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42851510	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42868902	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	43868104	MERCK & CO., INC.	OWN	
870.7485	Metabolism and pharmacokinetics	42743640	MERCK & CO., INC.	OWN	
870.7485	Metabolism and pharmacokinetics	42743641	MERCK & CO., INC.	OWN	
870.7485	Metabolism and pharmacokinetics	44030601	MERCK & CO., INC.	OWN	
870.7600	Dermal penetration	43850113	MERCK & CO., INC.	OWN	
810.1000	Product Performance. Overview, Definitions and Gen	47465501	SYNGENTA	OWN	
810.1000	Product Performance. Overview, Definitions and Gen	47691001	SYNGENTA	OWN	
810.1000	Product Performance. Overview, Definitions and Gen	47878901	SYNGENTA	OWN	

Thomas J Parshley

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DATA MATRIX

Date: 2/10/2010	Reg. No: 100-1309	Page 9 of 16
Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: Emamectin Benzoate 4.0% Tree Injection	

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
850.4400	Aquatic plant toxicity test using Lemna spp. Tiers I an	43850108	MERCK & CO., INC.	OWN	
850.4400	Aquatic plant toxicity test using Lemna spp. Tiers I an	43850109	MERCK & CO., INC.	OWN	
850.5400	Algal toxicity, Tiers 1 and 2	43850108	MERCK & CO., INC.	OWN	
850.5400	Algal toxicity, Tiers 1 and 2	43850109	MERCK & CO., INC.	OWN	
875.2100	Foliar dislodgeable residue dissipation	43850126	MERCK & CO., INC.	OWN	
875.2100	Foliar dislodgeable residue dissipation	44007903	MERCK & CO., INC.	OWN	
875.2200	Soil residue dissipation	43850126	MERCK & CO., INC.	OWN	
875.2200	Soil residue dissipation	44007903	MERCK & CO., INC.	OWN	
875.2400	Dermal exposure	43850126	MERCK & CO., INC.	OWN	
875.2400	Dermal exposure	43943301	MERCK & CO., INC.	OWN	
875.2600	Biological Monitoring	43943301	MERCK & CO., INC.	OWN	
850.3020	Honey bee acute contact toxicity	42851530	MERCK & CO., INC.	OWN	

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Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: Emamectin Benzoate 4.0% Tree Injection	

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
850.3030	Honey bee toxicity of residues on foliage	43393006	MERCK & CO., INC.	OWN	
161-1	Hydrolysis - laboratory	42743642	MERCK & CO., INC.	OWN	
161-2	Photodegradation in water - laboratory	43404301	MERCK & CO., INC.	OWN	
161-2	Photodegradation in water - laboratory	43850114	MERCK & CO., INC.	OWN	
161-3	Photodegradation in soil - laboratory	43404302	MERCK & CO., INC.	OWN	
161-3	Photodegradation in soil - laboratory	44010001	MERCK & CO., INC.	OWN	
161-4	Photodegradation in Air	44007906	MERCK & CO., INC.	OWN	
161-4	Photodegradation in Air	44007907	MERCK & CO., INC.	OWN	
162-1	Aeroic Soil metabolism	43235101	MERCK & CO., INC.	OWN	
162-1	Aeroic Soil metabolism	43404303	MERCK & CO., INC.	OWN	
162-1	Aeroic Soil metabolism	43850115	MERCK & CO., INC.	OWN	
162-1	Aeroic Soil metabolism	44007905	MERCK & CO., INC.	OWN	

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Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: Emamectin Benzoate 4.0% Tree Injection	

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
162-1	Aeroic Soil metabolism	44010001	MERCK & CO., INC.	OWN	
162-2	Anaerobic Soil Metabolism	43850116	MERCK & CO., INC.	OWN	
163-1	Leaching and adsorption/desorption -- laboratory	42743643	MERCK & CO., INC.	OWN	
163-1	Leaching and adsorption/desorption -- laboratory	43850117	MERCK & CO., INC.	OWN	
164-1	Soil dissipation -- field	43404304	MERCK & CO., INC.	OWN	
164-1	Soil dissipation -- field	43850118	MERCK & CO., INC.	OWN	
860.1300	Nature of the residue -- plants, livestock	44007906	MERCK & CO., INC.	OWN	
860.1300	Nature of the residue -- plants, livestock	44007907	MERCK & CO., INC.	OWN	
850.1010	Aquatic invertigrate acute toxicity test, freshwater dap	42743603	MERCK & CO., INC.	OWN	
850.1010	Aquatic invertigrate acute toxicity test, freshwater dap	44007901	MERCK & CO., INC.	OWN	
850.1025	Oyster acute toxicity test (shell deposition)	43393001	MERCK & CO., INC.	OWN	
850.1025	Oyster acute toxicity test (shell deposition)	43393002	MERCK & CO., INC.	OWN	

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Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
850.1025	Oyster acute toxicity test (shell deposition)	43393003	MERCK & CO., INC.	OWN	
850.1025	Oyster acute toxicity test (shell deposition)	44007912	MERCK & CO., INC.	OWN	
850.1025	Oyster acute toxicity test (shell deposition)	44007913	MERCK & CO., INC.	OWN	
850.1025	Oyster acute toxicity test (shell deposition)	44007914	MERCK & CO., INC.	OWN	
850.1035	Mysid acute toxicity test	43393001	MERCK & CO., INC.	OWN	
850.1035	Mysid acute toxicity test	43393002	MERCK & CO., INC.	OWN	
850.1035	Mysid acute toxicity test	43393003	MERCK & CO., INC.	OWN	
850.1035	Mysid acute toxicity test	44007912	MERCK & CO., INC.	OWN	
850.1035	Mysid acute toxicity test	44007913	MERCK & CO., INC.	OWN	
850.1035	Mysid acute toxicity test	44007914	MERCK & CO., INC.	OWN	
850.1045	Penaeid acute toxicity test	43393001	MERCK & CO., INC.	OWN	
850.1045	Penaeid acute toxicity test	43393002	MERCK & CO., INC.	OWN	

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Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
850.1045	Penaeid acute toxicity test	43393003	MERCK & CO., INC.	OWN	
850.1045	Penaeid acute toxicity test	44007912	MERCK & CO., INC.	OWN	
850.1045	Penaeid acute toxicity test	44007913	MERCK & CO., INC.	OWN	
850.1045	Penaeid acute toxicity test	44007914	MERCK & CO., INC.	OWN	
850.1055	Bivalve acute toxicity test (embryo larval)	43393001	MERCK & CO., INC.	OWN	
850.1055	Bivalve acute toxicity test (embryo larval)	43393002	MERCK & CO., INC.	OWN	
850.1055	Bivalve acute toxicity test (embryo larval)	43393003	MERCK & CO., INC.	OWN	
850.1055	Bivalve acute toxicity test (embryo larval)	44007912	MERCK & CO., INC.	OWN	
850.1055	Bivalve acute toxicity test (embryo larval)	44007913	MERCK & CO., INC.	OWN	
850.1055	Bivalve acute toxicity test (embryo larval)	44007914	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	42743602	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	42851529	MERCK & CO., INC.	OWN	

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Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
850.1075	Fish acute toxicity test, freshwater and marine	43393001	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	43393002	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	43393003	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	43850106	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	44007912	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	44007913	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	44007914	MERCK & CO., INC.	OWN	
850.1300	Daphnid chronic toxicity test	43393004	MERCK & CO., INC.	OWN	
850.1300	Daphnid chronic toxicity test	43850107	MERCK & CO., INC.	OWN	
850.1300	Daphnid chronic toxicity test	44305601	MERCK & CO., INC.	OWN	
850.1300	Daphnid chronic toxicity test	45833001	SYNGENTA	OWN	
850.1350	Mysid chronic toxicity test	43393004	MERCK & CO., INC.	OWN	

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Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
850.1350	Mysid chronic toxicity test	43850107	MERCK & CO., INC.	OWN	
850.1350	Mysid chronic toxicity test	44305601	MERCK & CO., INC.	OWN	
850.1350	Mysid chronic toxicity test	45833001	SYNGENTA	OWN	
850.1400	Fish early-life stage toxicity test	43393004	MERCK & CO., INC.	OWN	
850.1400	Fish early-life stage toxicity test	43850107	MERCK & CO., INC.	OWN	
850.1400	Fish early-life stage toxicity test	44305601	MERCK & CO., INC.	OWN	
850.1400	Fish early-life stage toxicity test	45833001	SYNGENTA	OWN	
850.1710	Oyster BCF	43393005	MERCK & CO., INC.	OWN	
850.1730	Accumulation in fish -- waiver	43393005	MERCK & CO., INC.	OWN	
850.1850	Aquatic organism accumulation	43393005	MERCK & CO., INC.	OWN	
850.2100	Avian acute oral toxicity test	42743601	MERCK & CO., INC.	OWN	
850.2100	Avian acute oral toxicity test	42868905	MERCK & CO., INC.	OWN	

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Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
850.2200	Avian dietary toxicity test	42851527	MERCK & CO., INC.	OWN	
850.2200	Avian dietary toxicity test	42851528	MERCK & CO., INC.	OWN	
850.2300	Avian reproduction test	43850104	MERCK & CO., INC.	OWN	
850.2300	Avian reproduction test	43850105	MERCK & CO., INC.	OWN	
850.2300	Avian reproduction test	44007910	MERCK & CO., INC.	OWN	
850.2300	Avian reproduction test	44007911	MERCK & CO., INC.	OWN	

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Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: Emamectin Benzoate 4.0% Tree Injection	

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			AGRICULTURAL HAN	PER	
			AGRICULTURAL REE	PER	
			FIFRA ENDANGERED	PER	
			OUTDOOR RESIDENT	PER	
			RESIDENTIAL EXPOS	PER	
			SPRAY DRIFT TF	PER	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	

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Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	

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Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	

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Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	

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Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	

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Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			SYNGENTA	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street
WASHINGTON, D.C. 20460

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DATA MATRIX

Date: 2/10/2010	Reg. No: 100-1309	Page 7 of 16
Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: Emamectin Benzoate 4.0% Tree Injection	

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	

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Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: Emamectin Benzoate 4.0% Tree Injection	

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	

Thomas J Parshley — Thomas J. Parshley, NAFTA Senior Regulatory Product Manager — Date: 2/10/2010

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Date: 2/10/2010	Reg. No: 100-1309	Page 9 of 16
Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: Emamectin Benzoate 4.0% Tree Injection	

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	

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Date: 2/10/2010	Reg. No: 100-1309	Page 10 of 16
Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: Emamectin Benzoate 4.0% Tree Injection	

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	

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Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	

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Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: Emamectin Benzoate 4.0% Tree Injection	

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	

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Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: Emamectin Benzoate 4.0% Tree Injection	

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	

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Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: Emamectin Benzoate 4.0% Tree Injection	

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			SYNGENTA	OWN	
			MERCK & CO., INC.	OWN	

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Date: 2/10/2010	Reg. No: 100-1309	Page 15 of 16
Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: Emamectin Benzoate 4.0% Tree Injection	

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			SYNGENTA	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			SYNGENTA	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	

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Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	

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DATA MATRIX

Date: 2/10/2010	Reg. No: 100-902	Page 1 of 19
Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: EMAMECTIN BENZOATE TECHNICAL	

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
Cite-All	Cite-All	Cite-All (AHE	AGRICULTURAL HAN	PER	
Cite-All	Cite-All	Cite-All (ART	AGRICULTURAL REE	PER	
Cite-All	Cite-All	Cite-All (FES	FIFRA ENDANGERED	PER	
Cite-All	Cite-All	Cite-All (ORE	OUTDOOR RESIDENT	PER	
Cite-All	Cite-All	Cite-All (REJ	RESIDENTIAL EXPOS	PER	
Cite-All	Cite-All	Cite-All (SDT	SPRAY DRIFT TF	PER	
830.0000	Product identity and composition	44883705	SYNGENTA	OWN	
830.1600	Description of materials used to produce the product	44883701	SYNGENTA	OWN	
830.1620	Description of production process	44883701	SYNGENTA	OWN	
830.1650	Description of Formulation process	44883701	SYNGENTA	OWN	
830.7000	pH	44883702	SYNGENTA	OWN	
830.7550	Partition coefficient (n-octanol/water), shake falsk met	44883703	SYNGENTA	OWN	

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DATA MATRIX

Date: 2/10/2010	Reg. No: 100-902	Page 2 of 19
Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: EMAMECTIN BENZOATE TECHNICAL	

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
830.7560	Partition coefficient (n-octanol/water), generator colu	44883703	SYNGENTA	OWN	
830.7570	Partition coefficient (n-octanol/water), estimation by li	44883703	SYNGENTA	OWN	
830.7840	Water salubility: column elution method, shake flask	44883704	SYNGENTA	OWN	
830.7860	Water solubility: generator column method	44883704	SYNGENTA	OWN	
850 Series	Ecological Effects	47767401	SYNGENTA	OWN	
870.1100	Acute oral toxicity	42743605	MERCK & CO., INC.	OWN	
870.1100	Acute oral toxicity	42743612	MERCK & CO., INC.	OWN	
870.1100	Acute oral toxicity	42743613	MERCK & CO., INC.	OWN	
870.1100	Acute oral toxicity	42851502	MERCK & CO., INC.	OWN	
870.1100	Acute oral toxicity	42851518	MERCK & CO., INC.	OWN	
870.1100	Acute oral toxicity	42851519	MERCK & CO., INC.	OWN	
870.1100	Acute oral toxicity	43824003	MERCK & CO., INC.	OWN	

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Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: EMAMECTIN BENZOATE TECHNICAL	

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
870.1100	Acute oral toxicity	44007915	MERCK & CO., INC.	OWN	
870.1100	Acute oral toxicity	47002104	SYNGENTA	OWN	
870.1100	Acute oral toxicity	47002105	SYNGENTA	OWN	
870.1100	Acute oral toxicity	47153906	SYNGENTA	OWN	
870.1100	Acute oral toxicity	47153907	SYNGENTA	OWN	
870.1100	Acute oral toxicity	47309303	SYNGENTA	OWN	
870.1200	Acute dermal toxicity	42743606	MERCK & CO., INC.	OWN	
870.1200	Acute dermal toxicity	43824004	MERCK & CO., INC.	OWN	
870.1200	Acute dermal toxicity	43850111	MERCK & CO., INC.	OWN	
870.1200	Acute dermal toxicity	43869401	MERCK & CO., INC.	OWN	
870.1200	Acute dermal toxicity	47002106	SYNGENTA	OWN	
870.1200	Acute dermal toxicity	47153907	SYNGENTA	OWN	

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Date: 2/10/2010	Reg. No: 100-902	Page 4 of 19
Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: EMAMECTIN BENZOATE TECHNICAL	

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
870.1200	Acute dermal toxicity	47153908	SYNGENTA	OWN	
870.1200	Acute dermal toxicity	47309304	SYNGENTA	OWN	
870.1300	Acute inhalation toxicity	42743608	MERCK & CO., INC.	OWN	
870.1300	Acute inhalation toxicity	43868101	MERCK & CO., INC.	OWN	
870.1300	Acute inhalation toxicity	43868102	MERCK & CO., INC.	OWN	
870.1300	Acute inhalation toxicity	47002107	SYNGENTA	OWN	
870.1300	Acute inhalation toxicity	47153907	SYNGENTA	OWN	
870.1300	Acute inhalation toxicity	47309305	SYNGENTA	OWN	
870.2400	Acute eye irritation	42743615	MERCK & CO., INC.	OWN	
870.2400	Acute eye irritation	43824005	MERCK & CO., INC.	OWN	
870.2400	Acute eye irritation	43850112	MERCK & CO., INC.	OWN	
870.2400	Acute eye irritation	47002108	SYNGENTA	OWN	

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DATA MATRIX

Date: 2/10/2010	Reg. No: 100-902	Page 5 of 19
Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: EMAMECTIN BENZOATE TECHNICAL	

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
870.2400	Acute eye irritation	47153907	SYNGENTA	OWN	
870.2400	Acute eye irritation	47153909	SYNGENTA	OWN	
870.2400	Acute eye irritation	47309306	SYNGENTA	OWN	
870.2500	Acute dermal irritation	42743607	MERCK & CO., INC.	OWN	
870.2500	Acute dermal irritation	42743616	MERCK & CO., INC.	OWN	
870.2500	Acute dermal irritation	47002109	SYNGENTA	OWN	
870.2500	Acute dermal irritation	47153907	SYNGENTA	OWN	
870.2500	Acute dermal irritation	47153910	SYNGENTA	OWN	
870.2500	Acute dermal irritation	47309307	SYNGENTA	OWN	
870.2600	Skin sensitization	42743609	MERCK & CO., INC.	OWN	
870.2600	Skin sensitization	42743610	MERCK & CO., INC.	OWN	
870.2600	Skin sensitization	42743617	MERCK & CO., INC.	OWN	

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Date: 2/10/2010	Reg. No: 100-902	Page 6 of 19
Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: EMAMECTIN BENZOATE TECHNICAL	

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
870.2600	Skin sensitization	47002110	SYNGENTA	OWN	
870.2600	Skin sensitization	47153907	SYNGENTA	OWN	
870.2600	Skin sensitization	47153911	SYNGENTA	OWN	
870.2600	Skin sensitization	47309308	SYNGENTA	OWN	
870.3100	90-Day oral toxicity	42743620	MERCK & CO., INC.	OWN	
870.3100	90-Day oral toxicity	42743621	MERCK & CO., INC.	OWN	
870.3100	90-Day oral toxicity	42743622	MERCK & CO., INC.	OWN	
870.3100	90-Day oral toxicity	42743623	MERCK & CO., INC.	OWN	
870.3100	90-Day oral toxicity	42794201	MERCK & CO., INC.	OWN	
870.3100	90-Day oral toxicity	43868103	MERCK & CO., INC.	OWN	
870.3150	Subchronic nonrodent oral toxicity - 90-day	42743620	MERCK & CO., INC.	OWN	
870.3150	Subchronic nonrodent oral toxicity - 90-day	42743621	MERCK & CO., INC.	OWN	

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Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
870.3150	Subchronic nonrodent oral toxicity - 90-day	42743622	MERCK & CO., INC.	OWN	
870.3150	Subchronic nonrodent oral toxicity - 90-day	42743623	MERCK & CO., INC.	OWN	
870.3150	Subchronic nonrodent oral toxicity - 90-day	42794201	MERCK & CO., INC.	OWN	
870.3150	Subchronic nonrodent oral toxicity - 90-day	43868103	MERCK & CO., INC.	OWN	
870.3200	Repeated dose dermal toxicity - 21/28 day	42743625	MERCK & CO., INC.	OWN	
870.3200	Repeated dose dermal toxicity - 21/28 day	44007902	MERCK & CO., INC.	OWN	
870.3700	Prenatal developmental toxicity study	42743631	MERCK & CO., INC.	OWN	
870.3700	Prenatal developmental toxicity study	42743632	MERCK & CO., INC.	OWN	
870.3700	Prenatal developmental toxicity study	42743634	MERCK & CO., INC.	OWN	
870.3700	Prenatal developmental toxicity study	42743635	MERCK & CO., INC.	OWN	
870.3700	Prenatal developmental toxicity study	42743636	MERCK & CO., INC.	OWN	
870.3800	Reproduction and fertility effects	42743633	MERCK & CO., INC.	OWN	

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Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
870.3800	Reproduction and fertility effects	42851511	MERCK & CO., INC.	OWN	
870.4100	Chronic toxicity	42743624	MERCK & CO., INC.	OWN	
870.4100	Chronic toxicity	42851510	MERCK & CO., INC.	OWN	
870.4100	Chronic toxicity	42868902	MERCK & CO., INC.	OWN	
870.4100	Chronic toxicity	43868104	MERCK & CO., INC.	OWN	
870.4200	Carcinogenicity	43868104	MERCK & CO., INC.	OWN	
870.4200	Carcinogenicity	43868105	MERCK & CO., INC.	OWN	
870.5000	Genetic Toxicity tests	42743637	MERCK & CO., INC.	OWN	
870.5000	Genetic Toxicity tests	42743638	MERCK & CO., INC.	OWN	
870.5000	Genetic Toxicity tests	42743639	MERCK & CO., INC.	OWN	
870.5000	Genetic Toxicity tests	42851512	MERCK & CO., INC.	OWN	
870.5000	Genetic Toxicity tests	42851513	MERCK & CO., INC.	OWN	

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Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
870.5000	Genetic Toxicity tests	42851514	MERCK & CO., INC.	OWN	
870.5000	Genetic Toxicity tests	42851515	MERCK & CO., INC.	OWN	
870.5000	Genetic Toxicity tests	42851516	MERCK & CO., INC.	OWN	
870.5000	Genetic Toxicity tests	42851517	MERCK & CO., INC.	OWN	
870.5100	Bacterial reverse mutation test	47002111	SYNGENTA	OWN	
870.6100	Acute and 28-day delayed neurotoxicity of organopho	42743611	MERCK & CO., INC.	OWN	
870.6100	Acute and 28-day delayed neurotoxicity of organopho	42743614	MERCK & CO., INC.	OWN	
870.6100	Acute and 28-day delayed neurotoxicity of organopho	42743626	MERCK & CO., INC.	OWN	
870.6100	Acute and 28-day delayed neurotoxicity of organopho	42743627	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42743618	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42743619	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42743624	MERCK & CO., INC.	OWN	

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Guideline Reference Number	Name	MRID	Submitter	Status	Notes
870.6200	Neurotoxicity screening battery	42743628	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42743629	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42743630	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42851503	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42851504	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42851505	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42851506	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42851507	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42851508	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42851509	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42851510	MERCK & CO., INC.	OWN	
870.6200	Neurotoxicity screening battery	42868902	MERCK & CO., INC.	OWN	

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Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
870.6200	Neurotoxicity screening battery	43868104	MERCK & CO., INC.	OWN	
870.7485	Metabolism and pharmacokinetics	42743640	MERCK & CO., INC.	OWN	
870.7485	Metabolism and pharmacokinetics	42743641	MERCK & CO., INC.	OWN	
870.7485	Metabolism and pharmacokinetics	44030601	MERCK & CO., INC.	OWN	
870.7600	Dermal penetration	43850113	MERCK & CO., INC.	OWN	
810.1000	Product Performance. Overview, Definitions and Gen	47153901	SYNGENTA	OWN	
810.1000	Product Performance. Overview, Definitions and Gen	47153902	SYNGENTA	OWN	
810.1000	Product Performance. Overview, Definitions and Gen	47465501	SYNGENTA	OWN	
810.1000	Product Performance. Overview, Definitions and Gen	47691001	SYNGENTA	OWN	
810.1000	Product Performance. Overview, Definitions and Gen	47878901	SYNGENTA	OWN	
810.3000	General Considerations for Efficacy of Invertebrate C	47153901	SYNGENTA	OWN	
810.3000	General Considerations for Efficacy of Invertebrate C	47153902	SYNGENTA	OWN	

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Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
810.3500	Premise Treatments	47153901	SYNGENTA	OWN	
810.3500	Premise Treatments	47153902	SYNGENTA	OWN	
810.3500	Premise Treatments	47153903	SYNGENTA	OWN	
850.4400	Aquatic plant toxicity test using Lemna spp. Tiers I an	43850108	MERCK & CO., INC.	OWN	
850.4400	Aquatic plant toxicity test using Lemna spp. Tiers I an	43850109	MERCK & CO., INC.	OWN	
850.5400	Algal toxicity, Tiers 1 and 2	43850108	MERCK & CO., INC.	OWN	
850.5400	Algal toxicity, Tiers 1 and 2	43850109	MERCK & CO., INC.	OWN	
875.2100	Foliar dislodgeable residue dissipation	43850126	MERCK & CO., INC.	OWN	
875.2100	Foliar dislodgeable residue dissipation	44007903	MERCK & CO., INC.	OWN	
875.2200	Soil residue dissipation	43850126	MERCK & CO., INC.	OWN	
875.2200	Soil residue dissipation	44007903	MERCK & CO., INC.	OWN	
875.2400	Dermal exposure	43850126	MERCK & CO., INC.	OWN	

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Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
875.2400	Dermal exposure	43943301	MERCK & CO., INC.	OWN	
875.2600	Biological Monitoring	43943301	MERCK & CO., INC.	OWN	
850.3020	Honey bee acute contact toxicity	42851530	MERCK & CO., INC.	OWN	
850.3030	Honey bee toxicity of residues on foliage	43393006	MERCK & CO., INC.	OWN	
161-1	Hydrolysis - laboratory	42743642	MERCK & CO., INC.	OWN	
161-2	Photodegradation in water - laboratory	43404301	MERCK & CO., INC.	OWN	
161-2	Photodegradation in water - laboratory	43850114	MERCK & CO., INC.	OWN	
161-3	Photodegradation in soil - laboratory	43404302	MERCK & CO., INC.	OWN	
161-3	Photodegradation in soil - laboratory	44010001	MERCK & CO., INC.	OWN	
162-1	Aeroic Soil metabolism	43235101	MERCK & CO., INC.	OWN	
162-1	Aeroic Soil metabolism	43404303	MERCK & CO., INC.	OWN	
162-1	Aeroic Soil metabolism	43850115	MERCK & CO., INC.	OWN	

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Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
162-1	Aeroic Soil metabolism	44007905	MERCK & CO., INC.	OWN	
162-1	Aeroic Soil metabolism	44010001	MERCK & CO., INC.	OWN	
162-2	Anaerobic Soil Metabolism	43850116	MERCK & CO., INC.	OWN	
163-1	Leaching and adsorption/desorption -- laboratory	42743643	MERCK & CO., INC.	OWN	
163-1	Leaching and adsorption/desorption -- laboratory	43850117	MERCK & CO., INC.	OWN	
164-1	Soil dissipation -- field	43404304	MERCK & CO., INC.	OWN	
164-1	Soil dissipation -- field	43850118	MERCK & CO., INC.	OWN	
850.1010	Aquatic invertigrate acute toxicity test, freshwater dap	42743603	MERCK & CO., INC.	OWN	
850.1010	Aquatic invertigrate acute toxicity test, freshwater dap	44007901	MERCK & CO., INC.	OWN	
850.1025	Oyster acute toxicity test (shell deposition)	43393001	MERCK & CO., INC.	OWN	
850.1025	Oyster acute toxicity test (shell deposition)	43393002	MERCK & CO., INC.	OWN	
850.1025	Oyster acute toxicity test (shell deposition)	43393003	MERCK & CO., INC.	OWN	

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Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
850.1025	Oyster acute toxicity test (shell deposition)	44007912	MERCK & CO., INC.	OWN	
850.1025	Oyster acute toxicity test (shell deposition)	44007913	MERCK & CO., INC.	OWN	
850.1025	Oyster acute toxicity test (shell deposition)	44007914	MERCK & CO., INC.	OWN	
850.1035	Mysid acute toxicity test	43393001	MERCK & CO., INC.	OWN	
850.1035	Mysid acute toxicity test	43393002	MERCK & CO., INC.	OWN	
850.1035	Mysid acute toxicity test	43393003	MERCK & CO., INC.	OWN	
850.1035	Mysid acute toxicity test	44007912	MERCK & CO., INC.	OWN	
850.1035	Mysid acute toxicity test	44007913	MERCK & CO., INC.	OWN	
850.1035	Mysid acute toxicity test	44007914	MERCK & CO., INC.	OWN	
850.1045	Penaeid acute toxicity test	43393001	MERCK & CO., INC.	OWN	
850.1045	Penaeid acute toxicity test	43393002	MERCK & CO., INC.	OWN	
850.1045	Penaeid acute toxicity test	43393003	MERCK & CO., INC.	OWN	

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Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
850.1045	Penaeid acute toxicity test	44007912	MERCK & CO., INC.	OWN	
850.1045	Penaeid acute toxicity test	44007913	MERCK & CO., INC.	OWN	
850.1045	Penaeid acute toxicity test	44007914	MERCK & CO., INC.	OWN	
850.1055	Bivalve acute toxicity test (embryo larval)	43393001	MERCK & CO., INC.	OWN	
850.1055	Bivalve acute toxicity test (embryo larval)	43393002	MERCK & CO., INC.	OWN	
850.1055	Bivalve acute toxicity test (embryo larval)	43393003	MERCK & CO., INC.	OWN	
850.1055	Bivalve acute toxicity test (embryo larval)	44007912	MERCK & CO., INC.	OWN	
850.1055	Bivalve acute toxicity test (embryo larval)	44007913	MERCK & CO., INC.	OWN	
850.1055	Bivalve acute toxicity test (embryo larval)	44007914	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	42743602	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	42851529	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	43393001	MERCK & CO., INC.	OWN	

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Guideline Reference Number	Name	MRID	Submitter	Status	Notes
850.1075	Fish acute toxicity test, freshwater and marine	43393002	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	43393003	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	43850106	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	44007912	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	44007913	MERCK & CO., INC.	OWN	
850.1075	Fish acute toxicity test, freshwater and marine	44007914	MERCK & CO., INC.	OWN	
850.1300	Daphnid chronic toxicity test	43393004	MERCK & CO., INC.	OWN	
850.1300	Daphnid chronic toxicity test	43850107	MERCK & CO., INC.	OWN	
850.1300	Daphnid chronic toxicity test	44305601	MERCK & CO., INC.	OWN	
850.1300	Daphnid chronic toxicity test	45833001	SYNGENTA	OWN	
850.1350	Mysid chronic toxicity test	43393004	MERCK & CO., INC.	OWN	
850.1350	Mysid chronic toxicity test	43850107	MERCK & CO., INC.	OWN	

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Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
850.1350	Mysid chronic toxicity test	44305601	MERCK & CO., INC.	OWN	
850.1350	Mysid chronic toxicity test	45833001	SYNGENTA	OWN	
850.1400	Fish early-life stage toxicity test	43393004	MERCK & CO., INC.	OWN	
850.1400	Fish early-life stage toxicity test	43850107	MERCK & CO., INC.	OWN	
850.1400	Fish early-life stage toxicity test	44305601	MERCK & CO., INC.	OWN	
850.1400	Fish early-life stage toxicity test	45833001	SYNGENTA	OWN	
850.1710	Oyster BCF	43393005	MERCK & CO., INC.	OWN	
850.1730	Accumulation in fish -- waiver	43393005	MERCK & CO., INC.	OWN	
850.1850	Aquatic organism accumulation	43393005	MERCK & CO., INC.	OWN	
850.2100	Avian acute oral toxicity test	42743601	MERCK & CO., INC.	OWN	
850.2100	Avian acute oral toxicity test	42868905	MERCK & CO., INC.	OWN	
850.2200	Avian dietary toxicity test	42851527	MERCK & CO., INC.	OWN	

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Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
850.2200	Avian dietary toxicity test	42851528	MERCK & CO., INC.	OWN	
850.2300	Avian reproduction test	43850104	MERCK & CO., INC.	OWN	
850.2300	Avian reproduction test	43850105	MERCK & CO., INC.	OWN	
850.2300	Avian reproduction test	44007910	MERCK & CO., INC.	OWN	
850.2300	Avian reproduction test	44007911	MERCK & CO., INC.	OWN	

Thomas J Parshley

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 2/10/2010

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: EMAMECTIN BENZOATE TECHNICAL	

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			AGRICULTURAL HAN	PER	
			AGRICULTURAL REE	PER	
			FIFRA ENDANGERED	PER	
			OUTDOOR RESIDENT	PER	
			RESIDENTIAL EXPOS	PER	
			SPRAY DRIFT TF	PER	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	

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Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
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Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			MERCK & CO., INC.	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	

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[redacted]			SYNGENTA	OWN	
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			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			SYNGENTA	OWN	

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			SYNGENTA	OWN	
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			MERCK & CO., INC.	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
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			SYNGENTA	OWN	
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			MERCK & CO., INC.	OWN	
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			MERCK & CO., INC.	OWN	
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			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
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			MERCK & CO., INC.	OWN	
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			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
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			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			SYNGENTA	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
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			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
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[redacted]			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	
			SYNGENTA	OWN	

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Ingredient: Emamectin Benzoate		

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			SYNGENTA	OWN	
			SYNGENTA	OWN	
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			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
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			MERCK & CO., INC.	OWN	
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Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
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[redacted]			MERCK & CO., INC.	OWN	
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			MERCK & CO., INC.	OWN	
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Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: 2/10/2010	Reg. No: 100-902	Page 18 of 19
Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: EMAMECTIN BENZOATE TECHNICAL	

Ingredient: Emamectin Benzoate

Guideline Reference Number	Name	MRID	Submitter	Status	Notes
[redacted]			MERCK & CO., INC.	OWN	
			SYNGENTA	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			SYNGENTA	OWN	
			MERCK & CO., INC.	OWN	
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			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	
			MERCK & CO., INC.	OWN	

Thomas J Parshley

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 2/10/2010

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date: 2/10/2010	Reg. No: 100-902	Page 19 of 19
Syngenta Crop Protection, P.O. Box 18300, Greensboro, NC 27419	Product: EMAMECTIN BENZOATE TECHNICAL	

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			MERCK & CO., INC.	OWN	

Thomas J Parshley

Thomas J. Parshley, NAFTA Senior Regulatory Product Manager

Date: 2/10/2010

(Master label)

RESTRICTED USE PESTICIDE
DUE TO ACUTE TOXICITY TO HUMANS
FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION, AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION.

Emamectin Benzoate 4.0% Tree Injection

Injected insecticide for two year control of listed arthropod pests in deciduous, coniferous, and palm trees~~ash trees (*Fraxinus* spp.)~~

Active Ingredient:	
Emamectin Benzoate[1]	4.0%
Other Ingredients:	96.0%
Total:	100.0%

[1]CAS No.155569-91-8
Contains 0.36 lbs. emamectin per gallon.

KEEP OUT OF REACH OF CHILDREN.

WARNING/AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

See additional precautionary statements and directions for use on label[in booklet].

EPA Reg. No. 100-1309

EPA Est. xxxxx

Product of xxxxx
Formulated in xxxxx

SCP 1309A-M(draft)

Net Contents

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING/AVISO

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear. Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID	
If in eyes	•Hold eye open and rinse slowly and gently with water for 15-20 minutes. •Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. •Call a poison control center or doctor for treatment advice.
If swallowed	•Call poison control center or doctor immediately for treatment advice. •Have person sip glass of water if able to swallow. •Do not induce vomiting unless told to do so by the poison control center or doctor. •Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN

Early signs of intoxication include dilation of pupils, muscular incoordination, and muscular tremors. Vomiting within one-half hour of exposure can minimize toxicity following accidental ingestion of the product; rapidly after exposure (< 15 minutes) administer repeatedly medical charcoal in a large quantity of water or ipecac. If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive parenteral fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels and proper respiratory functionality) as indicated by clinical signs, symptoms, and measurements. In severe cases, observations should continue for at least several days until clinical condition is stable and normal. Since emamectin benzoate is believed to enhance GABA activity in animals, it is probably wise to avoid drugs that enhance GABA activity (barbiturates, benzodiazepines, valproic acid) in patients with potentially toxic emamectin benzoate exposure.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
HOT LINE NUMBER For 24-Hour Medical Emergency Assistance (Human or Animal), Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident) Call **1-800-888-8372**

Personal Protective Equipment (PPE)

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Chemical–resistant gloves (Category C) such as barrier laminate; butyl rubber ≥14 mils; nitrile rubber ≥14 mils; or neoprene rubber ≥14 mils.
- Shoes and socks
- Protective eyewear

Environmental Hazards

This product is highly toxic to fish, mammals and aquatic invertebrates. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater. This product is highly toxic to bees exposed to direct treatment or residues on blooming trees.

Physical or Chemical Hazards

Do not use or store near heat or open flame.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, Inc. or Seller. To the extent permitted by applicable law, Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law: (1) this warranty does not extend to the use of the product contrary to label instructions or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and, (2) Buyer and User assume the risk of any such use. TO THE EXTENT PERMITTED BY APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.

To the extent permitted by applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.

DIRECTIONS FOR USE
RESTRICTED USE PESTICIDE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

IMPORTANT: Read entire label before using this product. Failure to follow label instructions may result in poor control or tree injury. Failure to follow label directions may cause injury to people, animals and environment.

APPLICATION TO TREES

Emamectin Benzoate 4.0% Tree Injection is for control of mature and immature arthropod pests of deciduous, coniferous, and palm trees ~~ash trees (*Fraxinus* spp.)~~, including, but not limited to, those growing in residential and commercial landscapes, parks, plantations, seed orchards, and forested sites (in private, municipal, state, tribal and national areas). Emamectin Benzoate 4.0% Tree Injection contains the active ingredient emamectin benzoate and is formulated to translocate in the tree's vascular system when injected. This product must be placed into active sapwood, and will actively control pests for up to two years.

USE DIRECTIONS

Emamectin Benzoate 4.0% Tree Injection is designed for use with tree injection devices that meet the label and dose requirements [(for example, the Arborjet Tree Injection Systems)] for the control of listed pests of trees. Follow manufacturer's directions for equipment use.

Dosages are based on the Diameter (in inches) of the tree at Breast Height (DBH"). Tree DBH is the outside bark diameter at breast height. Breast height is defined as 4.5 feet (1.37m) above the ground on the uphill side of the tree. For the purposes of determining breast height, the ground includes the duff layer that may be present, but does not include unincorporated woody debris that may rise above the ground line.

The diameter is determined by measuring the circumference of the tree at DBH", and dividing the circumference (in inches) by three (3). To determine DBH" for multi-stemmed woody ornamentals, measure the DBH" for each stem or branch and add together for the total DBH" per tree.

Placement of Application/Injection Sites: Inject at the base of the tree. Inject into the stem within 12" of the soil, into the trunk flare or into tree roots exposing them by shallow excavation. Make applications into intact, healthy sapwood. Do not inject into injured areas or areas with decay. Select injection sites associated with stem growth.

Number of Injection Sites: Work around the tree, spacing injection sites approximately every 6.0 inches of tree's circumference.

Drill Depth: Drill through the bark then 5/8" to 1-5/8" (hardwoods) or 1-5/8" to 2" (conifers) into the sapwood with the appropriate sized drill bit. Use clean, sharp drill bits. Brad point bits are recommended. Precautions should be taken to avoid diseased areas and transferring infected tissues to other injection sites.

Resinous Conifers

In resinous conifers, such as pine and spruce, start the injection immediately after drilling into the sapwood. A prolonged delay may reduce uptake on account of resin flow into opening.

WHEN TO TREAT

Emamectin Benzoate 4.0% Tree Injection contains the active ingredient emamectin benzoate which is a glycoside insecticide. It is active against immature and adult stages of arthropods. The primary route of toxicity is through ingestion.

ENVIRONMENTAL CONDITIONS: Uptake of Emamectin Benzoate 4.0% Tree Injection is dependent upon the tree's transpiration. Transpiration is dependent on a number of abiotic and biotic factors, such as soil moisture, soil and ambient temperature, and time of day. For uptake, apply when soil is moist, soil temperatures are above 45˚F, ambient temperatures are between 40˚ to 90˚F, and during the 24 hour period when transpiration is greatest, typically before 2:00 PM. Applications to drought or heat stressed trees may result in injury to tree tissue, poor treatment and subsequent control. Avoid treating trees that are moisture stressed or suffering from herbicide damage.

MONITOR TREE HEALTH and PEST INFESTATIONS: Effective injection treatment is favored by a full canopy (i.e., leaves) and healthy vascular system. Once these tissues are compromised by arthropod damage (larval galleries, defoliation, leaf mining, etc.) an effective and uniform application of Emamectin Benzoate 4.0% Tree Injection may be difficult to achieve and subsequent control may be poor. Optimally, treatment should be made preventively at least 2 to 3 weeks before arthropods historically infest the host tree. As a result of systemic movement and longevity of Emamectin Benzoate 4.0% Tree Injection in trees, this interval may be extended much earlier to 6 months should tree dormancy, adverse weather, management, asynchronous life cycle of pests, etc., allow earlier application timing.

Emamectin Benzoate 4.0% Tree Injection may also be effective as a remedial treatment against some pests, such as those with slower development or if multiple life stages are susceptible to Emamectin Benzoate 4.0% Tree Injection. Pests that attack the stem and branches such as bark beetles and clearwing borers may disrupt vascular tissue resulting in poor distribution in an infested tree. This includes the initial larval stages of pests, such as bark beetles and clearwing borers, that attack the stem and branches, which may disrupt vascular tissue resulting in poor distribution of the product in an

infested tree. However, control may be achieved if larvae come into contact or feed on Emamectin Benzoate 4.0% Tree Injection treated tissues.

USE

Use as formulated or dilute with equivalent 1 to 3 volumes of water or more, as necessary.

USE RATE TABLE

Tree Diameter (DBH) (Inches)	Low ml. product/tree	Medium ml. product/tree	Medium - High ml. product/tree	High ml. product/tree	Number of Injection Sites
4 to 6	15	25	50	-	3
7 to 9	20	40	80	-	4
10 to 12	30	55	110	165	5
13 to 15	35	70	140	210	6
16 to 18	40	75	150	225	7
19 to 21	50	100	200	300	8
22 to 24	-	115	230	345	10
25 to 27	-	130	260	390	11
28 to 30	-	145	290	435	12
31 to 33	-	160	320	480	13
34 to 36	-	175	350	525	15
37 to 39	-	190	380	570	16
40 to 42	-	205	410	615	17
43 to 45	-	220	440	660	18
46 to 48	-	235	470	705	20
49 to 51	-	250	500	750	21
52 to 54	-	265	530	795	22
55 to 57	-	280	560	840	23
58 to 60	-	295	590	885	25
61 to 63	-	310	620	930	26
64 to 66	-	325	650	975	27
67 to 69	-	340	680	1020	28
70 to 72	-	355	710	1065	30

The use of low, medium, medium high and high rates are based on the professional judgement of the applicator as to what constitutes a low, medium or high infestation.

Higher rates tend to provide longer residual and control of more difficult to control insects. See **Target Pest** for additional information in choosing the amount of product to apply.

Applications in Trees

Tree Tissue	Target Pest	Application Rate[1]	Comments
Seed and Cone	Pine Coneworm (*Dioryctria* spp) Pine Cone Seed Bug (suppression of *Leptoglossus* and *Tetyra* spp in the year of treatment)	Medium to High	For optimal control apply in the fall for early season pests or at least 30 days before insect attack.
Bud and Leaf	Tent Caterpillars (including Eastern, Forest, Pacific, and Western) Western Spruce Budworm Winter Moth	Low to Medium	Apply at least 2-3 weeks before the pest has historically been present. Consult with local extension agent for when this will occur in your area.
	Bagworm Fall Webworm Gypsy Moth Mimosa Webworm Oak Worm Tussock Moth Leafminers (including ~~Diptera,~~ Lepidoptera, Coleoptera, Hymenoptera) Honeylocust Plant Bug Pine Needle Scale Red Palm Mite Sawfly (including Elm, Pine)~~Orange-striped Oakworm~~	Low to High	
	~~**Mites:**~~ ~~Eryiophid mites~~ ~~European red mite~~ ~~Spruce spider mites~~ ~~Twospotted spider mite~~ ~~Sawfly~~ ~~Erythrina gall wasp~~	~~Low to High~~	
Shoot, Stem, Trunk and Branch	Clearwing Borers (including Ash, and Sequoia Pine Pitch Tube Moth) ~~Horntails~~	Low to Medium	For control apply at least 30 days before historical egg hatch or adult flight and to trees whose vascular tissue is not damaged. If vascular tissue is damaged or plugged by insect galleries, nematodes or fungi,
	~~**Buprestid Borers**~~ (Flat-headed Borers (including adult and larvae of Emerald Ash Borer~~, Bronze birch borer, two-lined chestnut borer~~)	Low to High	

Tree Tissue	Target Pest	Application Rate[1]	Comments
	~~Longhorn borers~~ (Roundheaded Borers ~~including Eucalyptus, Pine Sawyer;~~ (excluding Asian Longhorn Borer~~beetles~~) ~~Pales Weevil (*Hylobius pales*)~~ **Scolytids (bark beetles)** *Ips* Engraver Beetles Mountain Pine Beetle Southern Pine Beetle Spruce Beetle Western Pine Beetle ~~White pine weevil~~ Pine-wood Nematode	Medium to High	uniform treatment and control may not be achieved.

[1]Use medium to high rates for remedial and longer residual control.

Compatibility

Do not mix Emamectin Benzoate 4.0% Tree Injection before injection with other products such as insecticides, fungicides, plant growth regulators, surfactants, adjuvants, and fertilizers.

RESTRICTION

Do not apply to trees that may yield food consumed by humans or used in animal feed.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage

Store in a cool, dry place, away from children and pets. Keep from freezing.

Pesticide Disposal

Waste resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Handling

Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or mix tank and drain

for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use and disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration~~, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.~~

The Syngenta logo and the CP FRAME are trademarks of a Syngenta Group Company
©2010~~9~~ Syngenta

For non-emergency (e.g., current product information), call Syngenta Crop Protection at 1-800-334-9481.

Manufactured for:
Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, North Carolina 27419-8300

SCP 1309A-M(draft)

(Non-detachable container label)

RESTRICTED USE PESTICIDE
DUE TO ACUTE TOXICITY TO HUMANS
FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION, AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION.

Emamectin Benzoate 4.0% Tree Injection

Injected insecticide for the control of listed arthropod pests in deciduous, coniferous, and palm trees~~ash trees (*Fraxinus* spp.)~~

Active Ingredient:	
Emamectin Benzoate[1]	4.0%
Other Ingredients:	96.0%
Total:	100.0%

[1]CAS No.155569-91-8
Contains 0.36 lbs. emamectin per gallon.

KEEP OUT OF REACH OF CHILDREN.

WARNING/AVISO

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

See additional precautionary statements and directions for use in booklet.

EPA Reg. No. 100-1309

EPA Est. xxxxx

SCP 1309A-M(draft)

_____
Net Contents

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING/AVISO

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear. Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID	
If in eyes	•Hold eye open and rinse slowly and gently with water for 15-20 minutes. •Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. •Call a poison control center or doctor for treatment advice.
If swallowed	•Call poison control center or doctor immediately for treatment advice. •Have person sip glass of water if able to swallow. •Do not induce vomiting unless told to do so by the poison control center or doctor. •Do not give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN

Early signs of intoxication include dilation of pupils, muscular incoordination, and muscular tremors. Vomiting within one-half hour of exposure can minimize toxicity following accidental ingestion of the product; rapidly after exposure (< 15 minutes) administer repeatedly medical charcoal in a large quantity of water or ipecac. If toxicity from exposure has progressed to cause severe vomiting, the extent of resultant fluid and electrolyte imbalance should be gauged. Appropriate supportive parenteral fluid replacement therapy should be given, along with other required supportive measures (such as maintenance of blood pressure levels and proper respiratory functionality) as indicated by clinical signs, symptoms, and measurements. In severe cases, observations should continue for at least several days until clinical condition is stable and normal. Since emamectin benzoate is believed to enhance GABA activity in animals, it is probably wise to avoid drugs that enhance GABA activity (barbiturates, benzodiazepines, valproic acid) in patients with potentially toxic emamectin benzoate exposure.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
HOT LINE NUMBER For 24-Hour Medical Emergency Assistance (Human or Animal), Or Chemical Emergency Assistance (Spill, Leak, Fire or Accident) Call **1-800-888-8372**

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

Pesticide Storage
Store in a cool, dry place, away from children and pets. Keep from freezing.

Pesticide Disposal
Waste resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Handling
Non-refillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use and disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration~~, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke~~.

The Syngenta logo and the CP FRAME are trademarks of a Syngenta Group Company
©2010~~9~~ Syngenta
Manufactured for:
Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, North Carolina 27419-8300

SCP 1309A-M(draft)

Additional Info. 1000 - RGNO

Memorandum

Date: 6/9/09

To: PM 07, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:
- ☒ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 5, 2009

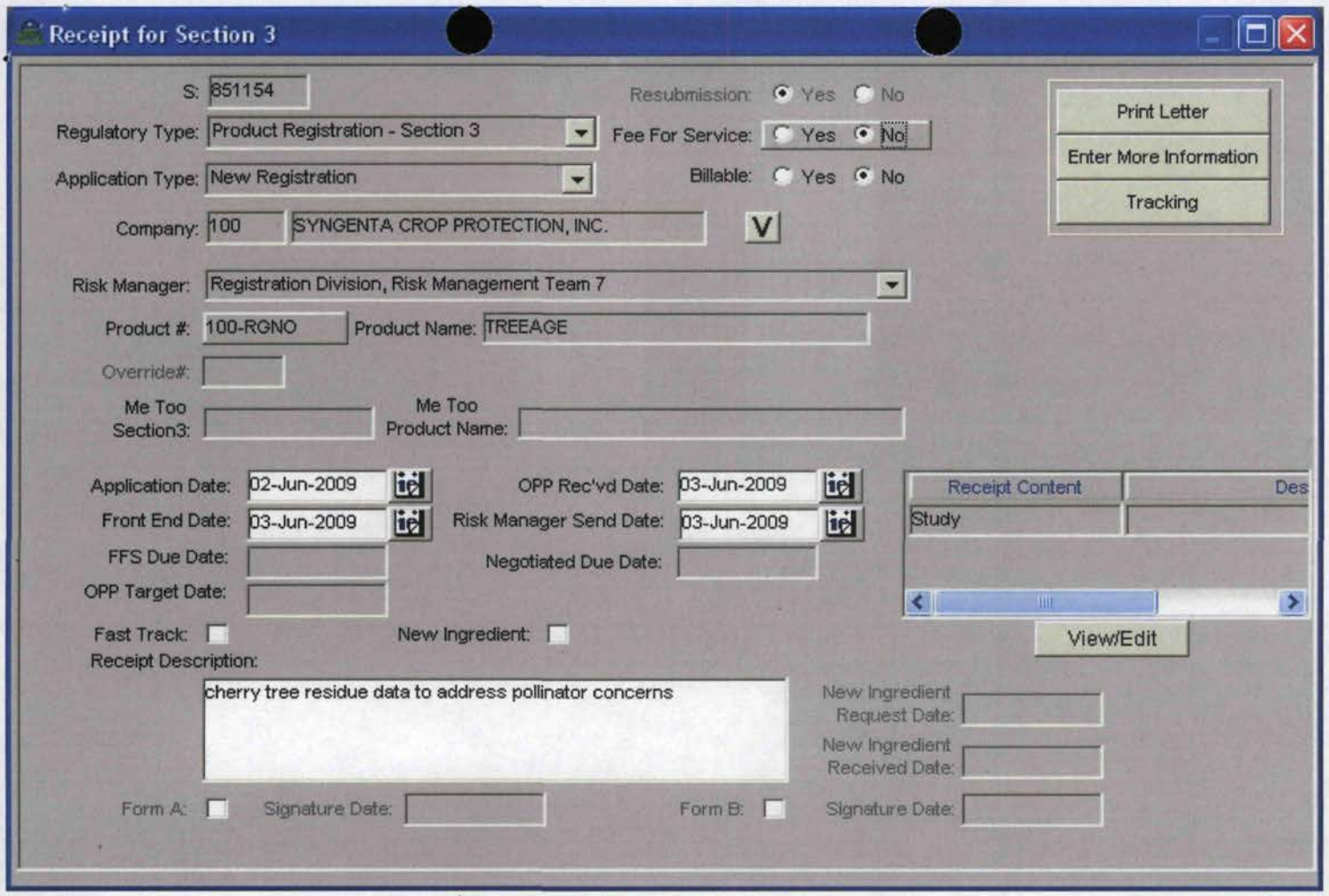
OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SYNGENTA CROP PROTECTION, INC.
ATTN: REGULATORY AFFAIRS
PO Box 18300
GREENSBORO, NC 27419-8300

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 03-JUN-09. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.


Receipt for Section 3
S: 851154
Resubmission: Yes No
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: New Registration
Billable: Yes No
Company: 100 SYNGENTA CROP PROTECTION, INC.
Print Letter
Enter More Information
Tracking
Risk Manager: Registration Division, Risk Management Team 7
Product #: 100-RGNO
Product Name: TREEAGE
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 02-Jun-2009
OPP Rec'vd Date: 03-Jun-2009
Front End Date: 03-Jun-2009
Risk Manager Send Date: 03-Jun-2009
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Des
Study
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
cherry tree residue data to address pollinator concerns
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

Syngenta Crop P[illegible]ion, Inc. Tel 336 632 6000
P.O. Box 18300
Greensboro, NC 27419-8300
www.syngenta.com

477674-00

syngenta

VIA FEDERAL EXPRESS

June 2, 2009

Document Processing Desk
Office of Pesticide Programs **(7505P)**
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Attention: Mr. Thomas Harris

SUBJECT: SUBMISSION OF CHERRY TREE RESIDUE DATA TO ADDRESS POLLINATOR CONCERNS IDENTIFIED FOR TREEÄGE, EPA FILE SYMBOL 100-RGNO

Dear Mr. Harris:

Enclosed please find three copies each of a transmittal document and a single data volume containing an additional non-GLP study and assessment of TREEäge (emamectin benzoate) residues in cherry trees. As we discussed, this information is being provided to help address concerns related to potential exposure of emamectin benzoate to pollinators, as identified in the EFED assessment for registration of the subject product.

Please note that Syngenta had discussed the possibility of also providing a listing of trees that bees are known to visit for pollination. While we had hoped this would be useful information, it has been determined not to be helpful because there is much uncertainty involved; while there are a number of basic research studies of pollinators and various tree species, it was generally not possible to ascertain from the literature which trees are definitely visited by pollinators, and how frequently. It was thus not possible to use this information to estimate actual pollinator exposure. In addition, we would like to touch on a recent discussion between Syngenta and EPA in which the Agency mentioned possible label language such as "do not apply to flowering trees." It appears that this language may be too general as most or all trees "flower" to some extent, and Syngenta suggests that such statements are not practical restrictions for tree uses.

Using the results from the residue analysis of cherry trees, Syngenta has assessed the potential risk to honey bees feeding on pollen with emamectin benzoate residues from tree injection use, and determined that this product is not likely to harm

syngenta

pollinators from either an acute or chronic toxicity perspective. Therefore, Syngenta believes that label restrictions such as proposed above are neither necessary nor practical for this product and use pattern. This assessment is part of the data volume as well.

Please contact me at (336) 632-7207 if there are any questions concerning this submission or the pending registration action for TREEäge.

Sincerely,

Thomas J Parshley

Thomas J. Parshley
NAFTA Senior Regulatory Product Manager
Syngenta Regulatory Affairs

Enclosed data submission

VOLUME 1 OF 2 OF SUBMISSION
(TRANSMITTAL DOCUMENT)

1. **Name and Address of Submitter**

Syngenta Crop Protection, Inc.
P.O. Box 18300
Greensboro, NC 27419

2. **Regulatory Action in Support of which this Package is Submitted**

Submission of Cherry Tree Residue Data to Address Pollinator Concerns Identified for Treeage, EPA File Symbol 100-PGNO

3. **Transmittal Date**

06/02/2009

4. **List of Submitted Studies**

MRID NUMBER	VOLUME NUMBER	STUDY TITLE	EPA GUIDELINE NUMBER
	1 OF 2	Transmittal Document	N/A
47767401	2 OF 2	Hazard Assessment of Emamectin Benzoate (Tree-Age®) Tree Injection to Pollinators, T001986-09, (MK244_50059)	N/A

Thomas J Parshley

COMPANY OFFICIAL: Thomas J. Parshley _____
(NAME) **(SIGNATURE)**

COMPANY NAME: SYNGENTA CROP PROTECTION, INC.

COMPANY CONTACT: Thomas J. Parshley (336) 632-7207
(NAME) (PHONE)

Head's up: Emamectin Benzoate - Pollinator Hazard Assessment (Tree-Age) Tree Injection 100-RGNO

Thomas Harris to: Dana Spatz, Brian Anderson 06/03/2009 03:39 PM

Cc: John Hebert, Venus Eagle, Meredith Laws

Dana, Brian:

re: 100-RGNO, Treeage, emamectin tree injection, PRIA due date 7/15/09

Below is an e-copy of a pollinator assessment just submitted for the above product. I will send you an official DP as soon as I get the paper copy with an MRID (usually takes 2-3 weeks). Given that the PRIA date is just over a month away, however, I wanted to share this e-copy in advance of the paper DP. I'll need your help with the pollinator label restrictions.

Your 1/13/09 eco risk assessment for this product discusses the unknowns concerning levels of emamectin in various tree parts (incl. pollen) after injection. We'll probably ask for studies on this as a condition of registration. I'm unclear, however, how toxic emamectin is to bees; do we even have studies on this?

The goal of reviewing the attached Syngenta pollinator assessment is to decide what labeling restrictions we want to impose on the label. Since there are already a dozen SLNs for use of Treeage to control emerald ash borer in ash trees there is a clear need for the product and I'd like to be able to register something by the 7/15/09 due date. I'd be glad to start out conservatively and expand as more data becomes available.

BTW, I've asked the registrant for an updated label. RD had already noted several items in the Directions for Use that needed clearer, more precise statements. I'll share a copy of the new label as soon as I get it. In the meantime, here's the initial draft label:

000100-0RNGO.20071220b.treeage.pdf

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----- Forwarded by Thomas Harris/DC/USEPA/US on 06/03/2009 03:17 PM -----

From:	<bunnie.konat@syngenta.com>
To:	Thomas Harris/DC/USEPA/US@EPA
Cc:	<tom.parshley@syngenta.com>
Date:	06/02/2009 01:18 PM
Subject:	Emamectin Benzoate - Hazard Assessment (Tree-Age) Tree Injection to Pollinators.pdf - Adobe Acrobat Professional

Dear Mr. Harris,

Tom Parshley has requested that I email you this letter (which includes the transmittal document) and the study volume. This is also being sent overnight to you today via FedEx.

Thank you,

Bunnie Konat
Syngenta Crop Protection, Inc.
Regulatory Affairs
P.O. Box 18300
Greensboro, NC 27419
336-632-5970

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Treeage Submission.pdf

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